ATTACHMENT 58

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/Counterclaim Defendant,

Case No. 3:21-cv-03496-VC

v.

INTUITIVE SURGICAL, INC.,

JURY TRIAL DEMANDED

Defendant/Counterclaim Plaintiff.

EXPERT ANTITRUST MERITS REBUTTAL REPORT OF LOREN K. SMITH, PH.D. January 18, 2023

HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

TABLE OF CONTENTS

I.	Int	roduction1		
	A.	Qualifications		
	B.	Assignment3		
	C.	Summary of Opinions		
II.	Background10			
	A.	Key Participants in Markets for Surgical Solutions		
	B.	The Evolution of Surgical Solutions for Soft Tissue Surgery14		
	C.	Intuitive's Innovation and Marketplace Competition		
		1. The Historical and Ongoing Development of Intuitive's Surgical Systems16		
		a. Intuitive's innovations have been focused on patient safety and improved outcomes		
		b. Intuitive complies with strict health and safety regulations20		
		c. From the outset, Intuitive tested its surgical system to ensure patients realize optimal outcomes		
		d. Since its inception, Intuitive has employed an integrated business model24		
		2. Intuitive competes to persuade doctors (and their patients) and hospitals to choose its product over other surgical solutions		
	D.	The History of SIS and Its EndoWrist Reset Service		
		1. SIS has been maintaining, repairing, and replacing medical equipment and continues to perform these activities		
		2. SIS's sales of Si EndoWrist instruments resets as a distributor for Rebotix Repair 29		
		e da Vinci Surgical System is a singular product focused on optimizing patient		
		ety and outcomes		
	A.	As critical complements in quality and reliability, the components of Intuitive's robotic surgical system are properly viewed as a single product		
		1. The da Vinci platform and its components are complements in the provision of surgical services		
		2. There are obvious and significant negative externalities associated with any non-controlled third-party sale of replacement instruments		
	B.	Intuitive designed the da Vinci Surgical System based on four "product pillars" that only can be achieved by the system as a whole		
	C.	From the beginning, Intuitive has been selling the da Vinci Surgical System as an integrated product		
		Intuitive designed the da Vinci Surgical System to be sold as an integrated product		
		2. Intuitive continuously has been selling the da Vinci Surgical System as an integrated product while innovating on various components		

	D.	Other manufacturers of robotic-assisted surgical systems also sell their systems as integrated products		
IV.	7. Plaintiff's asserted "tying" market should include laparoscopic and other surgical solutions			
		Dr. Lamb's Asserted "tying" Market and Proffered Support		
	В.	The proper analytical framework for assessing Intuitive's alleged monopoly power in the "Tying" market		
	C.	Surgical solutions are differentiated products		
	D.	The demand for da Vinci Surgical Systems is derived from the demand for surgeries and options available to hospitals and their doctors		
	E.	Relevant product markets should include a product's closest competitors59		
	F.	Dr. Lamb's assertion that Intuitive's margins reflect monopoly power is not supported by the evidence he provides69		
	G.	Dr. Lamb's evidence of a SSNIP test is inapt and demonstrates that Intuitive is not pricing as a monopolist		
V.	Intuitive's pricing in Plaintiff's asserted "tied" market does not reflect the abuse of monopoly power			
	A.	Intuitive's platform prices have not been increasing over time75		
	B.	Intuitive's instrument prices have not been increasing over time76		
	C.	Intuitive has not been price discriminating against any group of customers79		
VI.		has not been prevented from competing in the many legitimate markets for dical equipment maintenance and repair80		
	A.	Medical equipment repair services include many sales opportunities for independent service organizations		
	B.	SIS can and does compete in many legitimate markets for the repair of medical equipment		
VII		uitive's conduct has legitimate business justifications83		
		Bundling has procompetitive justifications		
	В.	Intuitive protects patients by selling an integrated product		
		1. Patients and surgeons benefit from Intuitive's best product and likely outcomes88		
		2. SIS (and third-party companies like it) potentially put patient safety and Intuitive's reputation at risk		
		3. Intuitive's reputation and future would be at risk if SIS and others were allowed to reset EndoWrist instruments		
	C.	Intuitive's sale of integrated systems has fostered procompetitive innovations and quality improvements		
	D.	Intuitive is able to offer customers a superior financial deal with an integrated product		

I. INTRODUCTION

A. QUALIFICATIONS

- My name is Loren K. Smith. I am a Principal at The Brattle Group and have been an economic
 consultant since April 2013. From September 2005 to March 2013, I was a staff economist at the
 U.S. Federal Trade Commission ("FTC"). I received my Ph.D. in economics from the University
 of Virginia in 2006.
- 2. I specialize in the application of economic and econometric tools to antitrust and competition matters. I have taught economics and econometrics to undergraduates and graduate students at the University of Virginia and Johns Hopkins University. I have taught courses on the application of economic and econometric tools to antitrust matters to lawyers and economists of foreign antitrust agencies in South Africa, Hungary, and Brazil, and at Fordham University. My research has been published in leading economics and antitrust journals, including the Journal of Applied Econometrics, the Journal of Economics and Management Strategy, and Antitrust Source.
- 3. While at the FTC, I led economic investigations into high-profile mergers and conduct matters, including in healthcare generally and medical devices, specifically. I also supported litigation and settlement efforts. Since leaving the FTC for private practice, I have consulted with clients on government investigations, federal merger challenges, and private litigations in a wide variety of industries, including healthcare, retail, lodging, medical devices, and various consumer products and intermediate goods.
- 4. I have significant experience studying the economics of healthcare, including several matters that required detailed economic analyses of competition among healthcare suppliers and providers.

 On behalf of healthcare providers as well as for the government, I have analyzed the competitive impact of healthcare provider mergers, including numerous hospital mergers. I recently testified

as the economic expert for the Plaintiffs in FTC et al. v. Thomas Jefferson University et al. 1 Both at the FTC and in private practice, I have assessed unilateral conduct in the healthcare industry, including analyses of market definition, market power, conduct, effects and justifications.

- 5. I provided expert testimony in *Rebotix Repair LLC v. Intuitive Surgical, Inc.* and *Restore Robotics LLC, Restore Robotics Repair LLC, and Clif Parker Robotics LLC v. Intuitive Surgical, Inc.* In both cases, I submitted expert reports on (i) the profits to be disgorged from the plaintiffs and (ii) Intuitive's lost profits from the "[plaintiffs'] alleged false advertising, unfair competition, deceptive and unfair trade practices, and tortious interference with contract." I also submitted expert reports addressing, from an economics perspective, the plaintiffs' allegations that Intuitive engaged in conduct to "monopoliz[e] trade in the worldwide and domestic aftermarkets for service of da Vinci surgical robots and the worldwide and domestic aftermarkets for service and replacement of EndoWrist surgical robotic instruments." In *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, I submitted an expert report responding to the damages analysis of the plaintiff's expert.
- 6. My curriculum vitae, which provides additional details about my qualifications, including my prior testimony and publications, is provided in Exhibit A.

¹ 20-cv-03499, Pennsylvania Eastern District Court, September 15 and 16, and October 1, 2020.

Expert Report of Loren K. Smith, Ph.D., Restore Robotics LLC and Restore Robotics Repair LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55, August 20, 2021, ¶ 6. Expert Report of Loren K. Smith, Ph.D., Rebotix Repair LLC v. Intuitive Surgical, Inc., Case No. 8:20-cv-02274, July 26, 2021, ¶ 6.

Expert Rebuttal Report of Loren K. Smith, Ph.D., Restore Robotics LLC, Restore Robotics Repair LLC, and Clif Parker Robotics LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55, September 27, 2021, ¶ 7. Expert Antitrust Merits Report of Loren K. Smith, Ph.D., Rebotix Repair LLC v. Intuitive Surgical, Inc., Case No. 8:20-cv-02274, August 30, 2021, ¶ 7. Rebotix's claims did not include "service of da Vinci surgical robots."

Expert Damages Rebuttal Report of Loren K. Smith, Ph.D., *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021, ¶ 7.

7. I submitted an expert report in this matter on December 2, 2022 that "quantif[ies] (i) SIS's profits to be disgorged; and (ii) Intuitive's lost profits from SIS's alleged false advertising, unfair competition, deceptive and unfair trade practices, and tortious interference with contract." I am simultaneously to this Report submitting an expert report that reviews and analyzes "the expert report submitted by Mr. Richard F. Bero on behalf of SIS."

B. ASSIGNMENT

- 8. I have been asked to review and analyze, from an economic perspective, certain aspects of the Complaint filed by Surgical Instrument Service Company, Inc. ("SIS" or "Plaintiff"),⁷ including the assessment of the competitive implications of the challenged conduct, as well as the expert report submitted by Dr. Russell L. Lamb on behalf of the Plaintiff.⁸ In particular, the Complaint alleges that "Intuitive has gone to extraordinary efforts to leverage its monopoly power in robots for use in minimally invasive soft tissue surgery, the repair and support of those robotic systems, and its monopoly power in instruments for use with such robots to foreclose aftermarket repair of those instruments by any competitors," which "costs hospitals and patients at least 30-45% per instrument (which savings would increase over time) or hundreds of millions of dollars a year in a \$2.4 billion market, without any safety or technical justification."
- 9. In response to Dr. Lamb, this report focuses on the proper economic approach for assessing the competitive effects of the challenged conduct. I do not attempt to respond to every claim in the

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Expert Report of Loren K. Smith, Ph.D., *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, December 2, 2022 ("Smith Counterclaims Damages Report"), ¶ 7.

Expert Damages Rebuttal Report of Loren K. Smith, Ph.D., *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, January 18, 2023, ¶ 8. Expert Report of Richard F. Bero, CPA, CVA, *Surgical Instrument Service Company, Inc. vs. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, December 2, 2022 ("Bero Report").

Complaint, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 5:21-cv-03496-SK, May 10, 2021 ("Complaint").

Expert Report of Dr. Russell L. Lamb, *Surgical Instrument Service Company, Inc. vs. Intuitive Surgical, Inc.*, Case No. 5:21-cv-03496, December 2, 2022 ("Lamb Report").

⁹ Complaint, ¶ 110.

Complaint or in the Lamb Report. My lack of response to any particular claim does not indicate agreement.

- 10. A list of the materials that I considered in forming my opinions in this report is enclosed as Exhibit B.
- 11. The work presented in this report was conducted by me and staff at The Brattle Group working under my direction. The Brattle Group bills my time on this matter at \$875 per hour. Neither my compensation nor the compensation of The Brattle Group depends in any way on the outcome of this case.
- 12. My work in this matter is ongoing. I reserve the right to supplement my analyses and conclusions should any additional information be provided to me after the submission of this report.

C. SUMMARY OF OPINIONS

- 13. I evaluate the Plaintiff's claims based on the fundamental economic premise that vertical restraints (i.e., agreements between firms that operate at different levels of a supply chain), such as the challenged conduct pertaining to SIS's antitrust allegations here, can have procompetitive benefits and, in some circumstances, cause anticompetitive harms. ¹⁰ Hence, a proper analysis of the challenged conduct must explore whether the conduct causes any anticompetitive effects and, if so, whether those effects are outweighed by demonstrable procompetitive benefits. My analysis leads me to the conclusion that Intuitive's challenged conduct has not caused anticompetitive harm and, by contrast, has resulted in significant procompetitive benefits.
- 14. More specifically, based on my analysis of the Lamb Report, as well as my review of the record in this case, I have two main opinions:

The challenged conduct pertaining to SIS's antitrust allegations includes monopolization, attempted monopolization, tying, and exclusive dealing (Complaint cover page). The arguments presented in my report equally apply across SIS's antitrust allegations. In my Report, I use the term "challenged conduct" to refer to SIS's antitrust allegations unless otherwise indicated.

- The challenged conduct encourages Intuitive to invest in significant medical advances that are designed to enhance patient safety and clinical outcomes.
 - In economics, the challenged conduct is known to encourage innovations that benefit consumer health and wellbeing, especially when incentives to invest in such innovations can otherwise be dampened by opportunistic behavior, such as free-riding, by buyers and competitors.¹¹
 - Evidence indicates that Intuitive has been responsible for advances in surgical solutions
 that have improved clinical outcomes and patient wellbeing, and those important
 advances were made possible by Intuitive's significant continued investments in the da
 Vinci Surgical System.
 - In the absence of the challenged conduct, healthcare providers and third parties like SIS would have the incentive to engage in ex post opportunism, including engaging free-riding third parties who profit off of Intuitive's years of investments in the production of quality EndoWrist instruments by resetting instruments so that they can be resold to customers at lower prices than Intuitive's. By preventing this opportunistic behavior, the challenged conduct encourages Intuitive to continue making investments that it otherwise likely would not make.
- As a matter of economics, the challenged conduct promotes lower overall pricing than would prevail in its absence.
 - It is well understood in economics that selling complementary components of a singular product together can cause prices to be lower than they otherwise would be.
 - Absent the challenged conduct, companies like SIS would siphon off sales of EndoWrist instruments, which are an essential component of the da Vinci Surgical System. This

A "free rider" is a "[c]onsumer or producer who does not pay for a nonexclusive good in the expectation that others will." A "nonexclusive good" is a "[g]ood that people cannot be excluded from consuming, so that it is difficult or impossible to charge for its use." *See* Robert S. Pindyck and Daniel L. Rubinfeld, *Microeconomics, Eighth Edition* (New Jersey: Pearson Education, Inc., 2013), 690 and 693 ("Pindyck and Rubinfeld").

In the context of the case, third parties may take advantage of (or free ride on) Intuitive's investments without sharing in the costs. For more details, *see* Section VII.C.

unbundling of the strong complementarity between the da Vinci platform and EndoWrist instruments would erode the foundation on which Intuitive's value proposition to customers is built, which likely would cause prices to increase.

- 15. These main opinions are based on several supporting opinions, as follows:
 - The da Vinci Surgical System is a singular product focused on optimizing patient safety and outcomes.
 - The theoretical existence of separate economic markets for surgical robotic platforms specifically for use in soft tissue surgeries (or MIST surgical robots as Dr. Lamb calls them) and EndoWrist "repair and replacement" results only from opportunistic actions of the Plaintiff—resetting the use counters of the EndoWrist instruments and circumventing Intuitive's specifications for the devices. Indeed, Intuitive designed these EndoWrist instruments so that they would not be used more than the number of times prescribed by Intuitive and cleared by the U.S. Food and Drug Administration ("FDA").
 - Intuitive designed the da Vinci Surgical System to achieve certain goals in patient safety and clinical outcomes, which depend on the high-quality performance of all of the system's components and services. The components are critical complements in achieving good clinical outcomes, ensuring an excellent record for patient safety, and protecting Intuitive's reputation and financial viability.
 - Intuitive's strategy for maintaining strict control over the components of its system has
 not changed. Since at least 1999 when Intuitive began selling its first-generation system,
 Intuitive has sold the da Vinci Surgical System, including the robotic platform,
 instruments, and service, together through a single contract with its customers.
 - It is economically meaningful that other medical device manufacturers similarly sell their systems as singular products. For example, other, less prolific robotic surgical systems are marketed as a singular product.

- Plaintiff's asserted "tying" market should include laparoscopic and other surgical solutions. ¹² Even if one were to ignore the fact that Intuitive has never sold its robotic platform separately from the other components of the da Vinci Surgical System, a hypothetical market that includes da Vinci platforms should also include laparoscopic and open surgery.
 - The proper economic framework under which Intuitive's alleged monopoly power¹³ in
 Plaintiff's asserted "tying" market should be evaluated involves an assessment of whether
 Intuitive faces competition sufficient to ensure its incentives to price and innovate
 competitively.
 - The record is clear that Intuitive's main focus when selling its da Vinci Surgical System
 is to convince as many customers as possible to buy its system, and the primary
 competitive constraints to Intuitive in this endeavor are traditional laparoscopic and open
 surgeries.
 - As Intuitive succeeded in this competition, it did not price discriminate against those
 customers that used the da Vinci platform the most, an economic outcome that is
 consistent with a competitive marketplace.
- Intuitive's pricing in Plaintiff's asserted "tied" market does not reflect the abuse of monopoly power. The Plaintiff and Dr. Lamb argue that Intuitive's prices for EndoWrist instruments are "high." As a general matter of economics, in a market where there is differentiation across product offerings, it is difficult to learn much from a static evaluation

I use the term "surgical solution" to refer to a set of tools and/or techniques used to perform a surgical procedure. *See*, e.g., Intuitive Surgical, Inc. Form 10-K For the Fiscal Year Ended December 31, 2021 ("Intuitive 2021 Form 10-K") at p. 6 ("Intuitive brings nearly three decades of experience and technical innovation to our robotic-assisted surgical **solutions**.") (emphasis added) and Medtronic plc Form 10-K For the Fiscal Year Ended April 30, 2021 at p. 3 ("Medtronic plc, headquartered in Dublin, Ireland, is among the world's largest medical technology, services, and **solutions** companies.") (emphasis added).

¹³ I use the term "monopoly power" to encompass coercive market power that is significant enough to cause anticompetitive harm.

of price levels. ¹⁴ Moreover, it also is well understood to economists that a static evaluation of prices and margins as a measure of monopoly power is inappropriate where innovator firms take big risks with uncertain investments, as Intuitive has done over the past 25 years. A more informative analysis evaluates the extent to which a firm charges higher prices where it arguably has greater market power. In this case:

- Intuitive's prices for da Vinci platforms have not increased over time as its sales have grown.
- Intuitive's prices for EndoWrist instruments have not increased over time as its sales have grown.
- Intuitive's prices for EndoWrist instruments do not systematically vary across customers,
 regardless of the extent of their utilization of the da Vinci Surgical System.
- These empirical facts indicate that Intuitive continues to face similar competitive constraints today as it did when it entered the broad market for surgical solutions more than 20 years ago.
- The Plaintiff has not been prevented from competing in the many legitimate markets for medical equipment maintenance and repair.
 - One theory of anticompetitive harm that SIS might assert is that its inability to sell reset EndoWrist instruments¹⁵ has kept it below a scale of operation that is sufficient for it to compete effectively in the repair and replacement of medical devices. However, there is no evidence of such foreclosure in this case. There are many markets for medical device

A "static evaluation of price levels" is an analysis of pricing at a given point in time. For example, the calculation of price over marginal cost in a given year (or over a short time period of a few years) is a static evaluation of price levels.

I understand from counsel that Intuitive's position is that all of SIS's transactions involving the process of resetting the use counters for EndoWrist instruments resulted from unlawful conduct that Intuitive is challenging in its counterclaims. *See also* Defendant's Answer, Affirmative Defense, and Counterclaims, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, December 14, 2021 ("Counterclaims"), ¶ 79 at p. 60.

replacement and repair where SIS could apply its claimed expertise. Indeed, SIS does compete in several of these markets.

- Intuitive's conduct has legitimate business justifications. To the extent Intuitive's conduct has the potential to cause anticompetitive harm—which, again, it does not—any such effect should be considered against legitimate business reasons for the conduct, as to which Intuitive has many.
 - As a matter of economics, there are many procompetitive rationales for grouping components of a product together for sale (or "bundling"). ¹⁶ These include lowering transaction and compatibility costs for customers, protecting intellectual property ("IP"), and pricing efficiently to increase product demand.
 - The economic evidence indicates that selling its da Vinci Surgical System as a singular product has allowed Intuitive to maintain control over the quality of the service its system provides, which improves clinical outcomes and protects patient safety. Intuitive's commitment to clinical outcomes and patient safety is not purely philanthropic; these performance metrics are crucial to Intuitive's financial viability.
 - Dr. Lamb acknowledges Intuitive's significant investments in the da Vinci Surgical
 System, but ignores the mechanism by which the challenged conduct fostered those
 investments. That is, by protecting Intuitive's IP and fostering patient safety, the
 challenged conduct has promoted procompetitive investments in the da Vinci Surgical
 System.
 - Intuitive's challenged conduct also has allowed it to offer customers a superior financial deal relative to what they likely would receive if Intuitive was forced to unbundle its product.

¹⁶ The procompetitive business reasons for "bundling" here also apply to exclusive contracting.

II. BACKGROUND

- 16. From the outset, Intuitive "[designed] and [manufactured] the da Vinci Surgical System" to "[represent] a new generation of surgery" after open surgery and minimally invasive surgery ("MIS") that would benefit patients and surgeons. ¹⁷ As I discuss below, over the next 25 years, Intuitive not only developed and commercialized robotic-assisted surgery ("RAS") for soft tissue surgery, but Intuitive has also continued to innovate and advance its technology to achieve its mission of improving patient care and safety and of enabling surgeons to increase access to minimally invasive care. ¹⁸
- 17. The remainder of this section is organized as follows: First, I provide an overview of the key participants in markets for surgical solutions (Section A). Second, I briefly describe the evolution of soft tissue surgery through the "three generations of surgical techniques" (open surgery, MIS, and RAS) (Section B) with a focus on Intuitive's innovations and marketplace competition (Section C). Last, I summarize the history of SIS and ongoing repair services offered by its personnel for other medical equipment manufacturers (Section D).

A. KEY PARTICIPANTS IN MARKETS FOR SURGICAL SOLUTIONS

18. Markets for surgical solutions involve a number of participants that interact with each other in various ways. Four key participants are patients, surgeons, healthcare facilities (such as hospitals or ambulatory surgical centers), and medical equipment suppliers.

Intuitive Surgical, Inc. Form 10-K For the Fiscal Year Ended December 31, 2000 ("Intuitive 2000 Form 10-K") at p. 1.

DeSantis (in *Rebotix*) Dep. Tr. 59:3-9 ("A. ... You know, the company believes in putting patients first, providing technologies to surgeons that will help them help patients. So that's been our strategy, and that's been our mission. In doing that, you know, we've spent a lot of time and money and -- and effort and -- and developed the soft tissue robot."). *See also* Intuitive 2021 Form 10-K at p. 6 ("Intuitive is committed to advancing minimally invasive care through a comprehensive ecosystem of products and services. This ecosystem includes systems, instruments and accessories, learning, and services connected by a digital portfolio that enables precision and control, seamless interactions and experiences, and meaningful insights to drive better care.").

¹⁹ Intuitive 2000 Form 10-K at p. 2.

- 19. *Patients* receive surgical (or other medical) treatment to address a health condition, such as gallstones in one's gallbladder or bile duct. Their health and wellbeing are directly impacted by the outcome of the surgery, which includes both short-run effects (such as pain and fatigue) and long-run effects (such as prolonged complications). ²⁰ Patients and their families choose from among their treatment options, which may include different surgical techniques as well as alternatives to surgery, and often rely on expert knowledge from their physicians, surgeons, and/or care teams. ²¹
- 20. *Surgeons* are trained healthcare professionals who are responsible for "the preoperative diagnosis of the patient, for performing the operation, and for providing the patient with postoperative surgical care and treatment."²² They typically specialize in a specific field, such as urology or

²⁰ "Side Effects of Surgery," Cancer.Net, accessed January 16, 2023, https://www.cancer.net/navigating-cancer-care/how-cancer-treated/surgery/side-effects-surgery; Anna Pinto et al., "Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis," *BMJ Open* (2016): 1-23.

²¹ "Computer-Assisted Surgical Systems," U.S. Food and Drug Administration, accessed January 16, 2023, https://www.fda.gov/medical-devices/surgery-devices/computer-assistedsurgical-systems (Under "Recommendations for Patients and Health Care Providers about Robotically-Assisted Surgery:" "Robotically-assisted surgery is an important treatment option but may not be appropriate in all situations. Talk to your physician about the risks and benefits of robotically-assisted surgeries, as well as the risks and benefits of other treatment options."); "Gynecologic Surgery," Valley Medical Center, accessed January 11, 2023, https://www.valleymed.org/services/all-specialties/obgyn-services/gynecologic-surgery (Under "Robotic-Assisted Hysterectomy": "For most patients, robotic-assisted surgery can offer numerous potential benefits over traditional approaches to vaginal, laparoscopic or open abdominal hysterectomy, particularly when performing more challenging procedures like radical hysterectomy for gynecologic cancer...While radical hysterectomy or abdominal hysterectomy performed using a robotic system are considered safe and effective, these procedures may not be appropriate for every individual. Always ask your doctor about all treatment options, as well as their risks and benefits."); Franciscan-00055779 at -782 ("Hernia surgery can be done multiple ways, including minimally-invasive robotic surgery and laparoscopic surgery, as well as traditional open surgery. Not every patient is a candidate for minimally-invasive surgery. Your doctor will need to determine which procedure is best for you.").

[&]quot;What is the job description for surgeons?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/job-description.

gynecology.²³ Surgeons perform surgeries at healthcare facilities (such as hospitals) where they have privileges.²⁴ Some surgical techniques or procedures require additional training, which may involve specialized residency programs.²⁵ Based on their expertise, surgeons often make recommendations to patients on surgical options for treatment and decisions on how to perform a surgery.²⁶ Health insurers and patients typically pay professional fees to surgeons for their services.²⁷

[&]quot;What are the surgical specialties?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/specialties.

[&]quot;Statement on Credentialing and Privileging and Volume Performance Issues," American College of Surgeons, April 1, 2018, accessed January 16, 2023, https://www.facs.org/about-acs/statements/111-credentialing ("Privileging designates the specific surgical conditions and procedures that a surgeon will be allowed to manage and perform at a health care institution.").

²⁵ "How many years of postgraduate training do surgical residents undergo?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/training.

[&]quot;What is the job description for surgeons?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/job-description ("The surgeon is responsible for the preoperative diagnosis of the patient, for performing the operation, and for providing the patient with postoperative surgical care and treatment. The surgeon is also looked upon as the leader of the surgical team. During the course of an operation, the surgeon must make important decisions about the patient's health, safety, and welfare."); "Statements on Principles," American College of Surgeons, accessed January 16, 2023, https://www.facs.org/about-acs/statements/stonprin ("Because a team of specialists undertakes much of modern patient care, nonsurgeon physicians often may conduct the initial evaluation of patients. However, the surgeon bears the ultimate responsibility for determining the need for and the type of operation. In making this decision, the surgeon must give precedence to sound indications for the procedure over pressure by the patients or referring physicians or the financial incentive to perform the operation.").

[&]quot;Understanding your hospital bill," MedlinePlus, accessed January 16, 2023, https://medlineplus.gov/ency/patientinstructions/000881.htm ("A hospital bill will list the major charges from your visit. It lists the services you received (such as procedures and tests), as well as medicines and supplies. Most of time, you will get a separate bill for health care provider fees."). See also "Professional versus facility billing: What hospitalists must know," Larry Beresford, June 15, 2021, accessed January 16, 2023, https://www.the-hospitalist.org/hospitalist/article/241539/mixed-topics/professional-versus-facility-billing-what-hospitalists-must.

- 21. *Healthcare facilities*, such as hospitals and ambulatory surgery centers, are locations where healthcare services, including surgeries, are provided. To build out the facilities' capabilities and service offerings, healthcare facilities may make capital purchase decisions for, as examples, diagnostic or surgical equipment.²⁸ Healthcare facilities charge insurers and patients facility fees (that are separate from professional fees) for procedures performed at the hospital or center.²⁹
- 22. *Medical equipment suppliers* design, manufacture, and sell medical devices. Suppliers often market to patients, surgeons and healthcare providers.³⁰ Healthcare facilities are usually the direct purchaser of the equipment while surgeons often have influence with patients in the decision over treatment choice as well as the facilities' purchasing decisions.³¹

Intuitive-00285709 ("Trinity Health FY 17 Capital Guidance") at -711 and -714. One of the guiding Capital Management Principles of Trinity Health's FY Capital Guidance is "[c]apital requests that improve the quality of care, grow the business and strengthen the financial health of the Ministry will have the highest priority." Trinity Health allocates capital to a "Strategic/Growth" category to "expand or protect a Ministry's market position, create a distinct competitive advantage, enhance services to physicians and patients, increase volume, and improve service line profitability." *See also* "About Us," Trinity Health, accessed January 5, 2023, https://www.trinity-health.org/about-us/ ("Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and nearly 27,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services.").

²⁹ *See* fn. 27 above.

³⁰ Intuitive-00015458 at -462. *See also* Intuitive-00002138.

Intuitive-00356654 at -657. According to this Intuitive document, physicians and surgeons influence the customer timeline for buying capital. *See also* Cleve Holden, "How do hospitals make Purchasing Decisions?" LinkedIn, January 25, 2018, accessed January 11, 2023, https://www.linkedin.com/pulse/how-do-hospitals-make-purchasing-decisions-cleve-holden ("A wide range of individuals may take part in determining whether a hospital buys a certain product....Physicians tend to be mainly interested in maximizing treatment effectiveness and improving the patient experience, but a range of other interests come into play.") and ¶ 20 above.

B. THE EVOLUTION OF SURGICAL SOLUTIONS FOR SOFT TISSUE SURGERY

- 23. Prior to the commercialization of RAS techniques for soft tissue surgery, patients had the options of open surgery and MIS for treatment:³²
 - a. Open surgery involves "[creating] an incision large enough to allow a direct view of the operating field and the insertion of at least two human hands to manipulate the patient's tissues."³³ Open surgery has been performed at least since the early 19th century and was revolutionized with the advent of anesthesia and antisepsis in the second half of the 19th century.³⁴ Although open surgery has advantages such as precision (given the "extremely wide range of motion" of the human hand) and ease for the surgeon, the large incision can "create very significant trauma to the patient, resulting in long hospitalization and recovery times, high hospitalization costs, as well as significant pain and suffering."³⁵
 - b. MIS includes surgical techniques that are performed through small incisions or "ports." There are further divisions of techniques within MIS, such as laparoscopy, endoscopy, and colonoscopy. ³⁷ In particular, technological advances in laparoscopes spurred laparoscopic

³² Intuitive-00595673 at -677 and -678. See also Intuitive 2000 Form 10-K at pp. 2-4.

Intuitive 2000 Form 10-K at p. 2. *See also* "Methods of Surgery," Johns Hopkins Medicine, accessed January 5, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/methods-of-surgery ("Johns Hopkins Medicine").

Atul Gawande, "Two Hundred Years of Surgery," *The New England Journal of Medicine* 366 (2012): 1716-1723.

Intuitive 2000 Form 10-K at p. 2. *See also* "Exploring Surgery Options: Open vs. Minimally Invasive," Beaumont, accessed January 16, 2023, https://www.beaumont.org/health-wellness/blogs/exploring-surgery-options-open-vs-minimally-invasive.

³⁶ Intuitive 2000 Form 10-K at pp. 2-3. *See also* John Hopkins Medicine.

Laparoscopy is a "minimally invasive procedure in the belly cavity that uses a tube with a light and camera lens at the end (laparoscope) to examine organs and check for abnormalities." Endoscopy is a "test that uses a small, flexible tube with a light and a camera lens at the end (endoscope) to examine the inside of the hollow organs of the digestive tract." Colonoscopy is the "[e]valuation of the entire colon using an endoscope." *See* John Hopkins Medicine.

surgical techniques in the United States in the 1930s.³⁸ The development of video laparoscopes in the late 1970s and early 1980s, which some researchers deem as the "single most important technological advancement for complex laparoscopic surgery," led to further uptake of the technique in the 1980s and 1990s.³⁹ Laparoscopic surgery's advantages for the patient over open surgeries include "decreasing blood loss, pain, and discomfort" as well as lowering postoperative complications and reducing recovery time.⁴⁰

24. As laparoscopic surgeries gained popularity in the 1980s and 1990s, it became apparent that the technique "worked well for relatively simple surgical procedures" but was not widely adopted for "applications requiring complex reconstruction." These limitations of laparoscopic surgeries provided an opportunity for RAS. In late 1980s and early 1990s, several groups located across various universities and laboratories researched ways to "marry telerobotic technologies with minimally-invasive surgical techniques" that could address the "challenges that were being experienced" in MIS laparoscopic methods. One group consisted of Phil Green at SRI International, surgeons at Stanford University, and Dr. John Bowersox. SRI International would later license its "telepresence surgery technology" to Intuitive in 1995.

C. INTUITIVE'S INNOVATION AND MARKETPLACE COMPETITION

25. Intuitive was founded in 1995 with a vision to "commercialize a fundamentally new generation of technology for [MIS]."⁴⁵ The company sold its first da Vinci Surgical System in 1998 and

William Kelley, "The Evolution of Laparoscopy and the Revolution in Surgery in the Decade of the 1990s," *Journal of the Society of Laparoendoscopic Surgeons* 12, No. 4 (2008): 351 ("Kelley").

³⁹ Kelley at pp. 352-353. *See also* Intuitive-00270554 at -556.

Riaz Agha and Gordon Muir, "Does laparoscopic surgery spell the end of the open surgeon?" *Journal of the Royal Society of Medicine* 96, No. 11 (2003): 544.

⁴¹ Intuitive-00270554 at -556.

⁴² Intuitive-00270554 at -556 and -557.

⁴³ Intuitive-00270554 at -557.

⁴⁴ Intuitive-00270554 at -558; Intuitive-00595673 at -675.

⁴⁵ Intuitive-00595673 at -675.

obtained FDA clearance in the U.S. in 2000.⁴⁶ Since its first sale, the number of da Vinci Surgical System placements grew to 6,730 worldwide as of 2021.⁴⁷ While the number of da Vinci surgical procedures has also grown by more than 6-times (or 600 percent) between 2009 and 2021, evidence shows that da Vinci procedures still represent a small minority of surgical procedures.⁴⁸

26. Below, I summarize the historical and ongoing development of Intuitive's surgical systems (i.e., the da Vinci Surgical Systems) and the company's initial and ongoing efforts to compete with open and laparoscopic surgical techniques.

1. The Historical and Ongoing Development of Intuitive's Surgical Systems

a. Intuitive's innovations have been focused on patient safety and improved outcomes

Medtronic and TransEnterix (now known as Asensus Surgical) advertise that "[r]obotic [p]enetration" in the surgical procedures is less than 5 percent. *See* "Company Fact Sheet," Asensus Surgical, accessed January 5, 2023, https://asensus.com/sites/default/files/media-kit/Asensus%20Fact%20Sheet%20-%202021.pdf at p. 2; "Robotic-Assisted Surgery (RAS) Analyst Update," Medtronic, September 24, 2019, accessed January 12, 2023, https://investorrelations.medtronic.com/download/MDT+RAS+Investor+Update+09242019. pdf at p. 19.

See also Kyle H. Sheetz, Jake Claflin, and Justin B. Dimick, "Trends in the Adoption of Robotic Surgery for Common Surgical Procedures," *JAMA Network Open* 3, No. 1 (2020): 1-9. Researchers at University of Michigan School of Medicine found that, across procedures, use of robotic surgery increase from 1.8 percent in 2012 to 15.1 percent in 2018 among 73 Michigan hospitals that account for over 90 percent of surgical volume in the state.

Intuitive-00270554 at -558. Note that the first sale of the da Vinci Surgical System was 1998, and Intuitive "began marketing the *da Vinci* System in Europe in 1999" (at -558). In its 10-K filings, Intuitive reports that the launch of the system was 1999 (e.g., Intuitive 2020 Form 10-K at p. 4).

⁴⁷ Intuitive 2021 Form 10-K at p. 12.

⁴⁸ 6.74 = (1,594,000– 206,000) / 206,000. The number of procedures worldwide in 2009 was approximately 206,000 (Intuitive 2010 Form 10-K at p. 44). The number of procedures in 2021 was approximately 1,594,000 worldwide (Intuitive 2021 Form 10-K at p. 63). *See also* Public Data Workpaper.

- 27. Intuitive's innovations focus on "advancing patient care in surgery" by "[improving] the quality of and access to minimally invasive care." When Intuitive formed in 1995, it recognized that there were limitations to laparoscopic surgery techniques—such as "[n]on-intuitive [i]nstrument [m]ovements," "[1]imited [d]egrees of [f]reedom," "[p]oor [s]ensory [f]eedback," and "[n]on-intuitive [v]isualization"—that prevented the benefits of MIS from reaching more patients and care teams. ⁵⁰ In the process of developing the first da Vinci Surgical System, engineers at Intuitive created two prototypes that, while demonstrating the concept of RAS, fell short on certain dimensions such as poor visualization, fragility, and unreliable instrument engagement. ⁵¹ In the words of Intuitive's Chief Product Officer (Bob DeSantis), Intuitive has "a rank order of priorities, and it's patients first." ⁵²
- 28. The da Vinci Surgical System includes "a surgeon's console, a patient-side cart, a high performance vision system and [Intuitive's] proprietary instruments." The surgeon's console is the place from which the surgeon "control[s] the motion of the surgical instruments that are situated at the patient side, as well as observe[s] video images from inside the patient." The patient-side cart is positioned next to the operating bed, and Intuitive's proprietary surgical instruments (including EndoWrist instruments) are attached to arms on the patient-side cart. 55

⁴⁹ Intuitive 2020 Form 10-K at p. 4.

⁵⁰ Intuitive-00595673 at -678 and -679.

Intuitive-00270554 at -560 through -563. Intuitive's Lenny SRI prototype was "not reliable—it was fragile—and the visualization provided by the combination of the Welch Allyn endoscope and the CrystalEyes display system was poor." Intuitive's Mona prototype suffered from "sensitiv[ity] to mechanical tolerances and lead to unreliable instrument engagement[,]" a "counterbalancing mechanism [that] proved to be unstable and inflexible," and unclear and uncomfortable stereo viewing of the surgical field due to insufficient image acquisition and display quality.

DeSantis (in *Rebotix*) Dep. Tr. 148:17-20 ("A. So we have a rank order of priorities, and it's patients first. Physicians, hospitals, employees, and investors are last. But we-- we try and – we try and benefit all of them.").

Intuitive 2000 Form 10-K at p. 1. As a shorthand in my report, I refer to the surgeon's console, patient-side cart, and vision cart as the "da Vinci platform."

Mahdi Azizian et al., "The da Vinci Surgical System," in *The Encyclopedia of Medical Robotics*, ed. Rajni Patel (New Jersey: World Scientific, 2018), 7 ("Azizian et al.").

⁵⁵ Intuitive 2000 Form 10-K at p. 6.

The vision system provides a high resolution, 3-D image of the patient's interior. ⁵⁶ Intuitive's proprietary instruments and accessories include EndoWrist instruments, which have "a wrist joint for natural dexterity" and come in a variety of end effectors (such as forceps and scissors). ⁵⁷ The surgical care team can use the instruments interchangeably during the procedure. ⁵⁸ Each EndoWrist instrument has a limited number of uses to ensure that "its performance meets specifications during each procedure." ⁵⁹

29. Since the 1990s, Intuitive has continued to innovate on the da Vinci Surgical System on multiple dimensions, and I highlight three examples here. First, the company has released four generations of the robotic platform: the original da Vinci Surgical System (sometimes referred to as the "Standard") in 1998, the da Vinci S system in 2006, the da Vinci Si system in 2009, and the da Vinci Xi system in 2014. ⁶⁰ These platforms improve on capabilities such as the range of procedures that can be performed. ⁶¹ Second, the company has developed a wide variety of instruments to enhance the system's capabilities and improve on precision. ⁶² Intuitive has also improved on the material of the instruments to increase durability and reduce instrument failures

⁵⁶ *Id*.

⁵⁷ *Id*.

⁵⁸ *Id*.

⁵⁹ *Id*.

[&]quot;Sustainability Report 2020," Intuitive Surgical, Inc., accessed January 16, 2023, https://isrg.gcs-web.com/static-files/15edd98b-4896-4bd7-a3b4-e2f095a61a61 at pp. 6-7 ("Intuitive 2020 Sustainability Report"). In addition, Intuitive launched the da Vinci X system in 2017 and da Vinci SP system in 2018 (Intuitive 2020 Sustainability Report at p. 7).

Intuitive 2020 Sustainability Report at pp. 6-7. In addition to receiving additional clearance for surgical procedures from the FDA, each generation improved the capabilities of the da Vinci Surgical System including 3DHD vision in 2007, EndoWrist Vessel Sealer and Firefly fluorescence imaging in 2011, and improvements to instruments and accessories.

[&]quot;Da Vinci Xi Single-Site Technology: Solutions for Single-Incision Surgery," Intuitive Surgical, accessed January 11, 2023, https://www.intuitive.com/en-us/-/media/Project/Intuitive-surgical/files/pdf/1025290ra-isi-brochure-single-site-digital-low-res-394110.pdf?la=en&hash=F24EC0B5DB9C62BDD688F77409A3CA50. For example, the da Vinci Xi 8mm endoscope provides "the surgeon a clearer view of the surgical field. FireFly fluorescence imaging is integrated to highlight specific tissues such as vessels and bile ducts." Some of the advantages of this endoscope include brighter image, higher resolution, and longer endoscope improving the Xi system's capabilities.

during operations.⁶³ Third, Intuitive has developed different financing arrangements for its customers, such as leasing and usage-based pricing.⁶⁴ By offering flexibility in the financing arrangements, Intuitive and its customers are able to increase access to the technology for patients.⁶⁵

30. Alongside its goal of improving on patient care and safety, Intuitive provides surgeons with "reliable and easy-to-use products" through its system design that allows for more natural surgeon movement, better ergonomics, and the reduction of tremors when compared with conventional MIS techniques such as traditional laparoscopy. 66 Intuitive's technology minimizes the invasiveness of RAS by "[transforming] the surgeon's natural hand movements outside of the body into corresponding micro-movements inside the patient's body" and "allow[ing] precision and control for delicate tasks." 67 These benefits to the surgeon also are designed to help to ensure better surgical outcomes for the patient. 68

Intuitive 2020 Sustainability Report at p. 12 ("To maximize customer benefits, we identified the most frequently used instruments by examining instrument usage data from millions of worldwide surgical procedures. Product teams enhanced instrument design, materials, manufacturing process, and testing protocols to improve instrument reliability over time. The teams addressed common reprocessing challenges, incorporating new design safeguards that improved durability."). See also DeSantis (in Restore) Dep. Tr. 53:1-12 (Q. ...Had you personally observed improvements in the quality and durability of the Xi instruments? A. Yes. Depending on what you mean by did I personally observe it; but uh-huh. Q. ...Had you personally seen return rates or other data to show that there were improvements in the quality and durability of the Xi instruments? A. Yes."); Vavoso (in Rebotix) Dep. Tr. 210:22-25 ("[A.] I can't give you a specific [design improvement that Intuitive implemented in response to RMAs from its consumers], but we are constantly innovating, looking to make those instruments more robust. ...[C]onstant innovation goes on with the instrument.").

Intuitive 2021 Form 10-K at p. 36 ("Certain of our leasing arrangements allow customers to cancel, return, or upgrade the systems leased prior to the end of the lease term without incurring a financial penalty. We also lease our systems to certain qualified customers where the lease payments are based on their usage of the systems.").

⁶⁵ See ¶ 137.f below.

⁶⁶ Intuitive 2021 Form 10-K at pp. 7, 10.

⁶⁷ Intuitive 2021 Form 10-K at p. 7.

Intuitive 2021 Form 10-K at p. 55 ("For over three decades, MIS has reduced trauma to patients by allowing selected surgeries to be performed through small ports rather than large incisions.... Da Vinci Surgical Systems enable surgeons to extend the benefits of MIS to

- b. Intuitive complies with strict health and safety regulations
- 31. From its inception, Intuitive has had to comply with strict health and safety regulations in all geographies where it sells the da Vinci Surgical System.⁶⁹ For example, in the U.S., Intuitive must obtain clearance from the Food and Drug Administration ("FDA") by procedure type to market the da Vinci Surgical System for use.⁷⁰ As part of the clearance process, Intuitive submitted "extensive testing data to the FDA" and "performance specifications."⁷¹ Post-clearance, the FDA performs "routine audits of companies" and "post market surveillance… activities" in which the FDA will "ask for testing and data."⁷² The process to achieve FDA

many patients who would otherwise undergo a more invasive surgery by using computational, robotic, and imaging technologies to overcome many of the limitations of traditional open surgery or conventional MIS.... In designing our products, we focus on making our technology easy and safe to use.").

Intuitive 2021 Form 10-K at pp. 14-15 ("Our products and operations are subject to regulation by the FDA, the State of California, and countries or regions in which we market our products. In addition, our products must meet the requirements of a large and growing body of international standards, which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use, and disposal of our products.").

Vavoso (*in Rebotix*) Dep. Tr. 86:6-11 ("A. It's that you receive a -- an approval to apply that technology to a given procedure type. So not every system out there can be compared to every system in terms of its applicability. One might have a more narrow applicability based on FDA approval. One might have a broader."). *See also* "Robotic-Assisted Surgery with da Vinci Systems," Intuitive, accessed January 17, 2023, https://www.intuitive.com/en-us/patients/da-vinci-robotic-surgery ("Da Vinci surgical systems are cleared by applicable regulatory agencies for use in several types of surgery.") and Azizian et al. at p. 5 ("This first FDA clearance was for applications in general surgery; however, additional indications for thoracoscopic (chest) and radical prostatectomy procedures followed one year later.").

Rosa (in *Restore*) Dep. Tr. 42:11-43:2 ("Q. As part of that process, does Intuitive provide its own testing data for the Endowrist instruments to the FDA? A. As part of the clearance process? Q. Yes. A. We provide extensive testing data to the FDA, yes. Q. As part of that clearance process, does Intuitive also disclose performance specifications for the Endowrist instruments to the FDA? A. I'm almost certain that our -- our requirements documents or the specifications as you're talking about them are part of that package.").

Rosa (in *Restore*) Dep. Tr. 39:19-40:14 ("Q. ...Once the FDA has cleared a medical device for marketing and sale by Intuitive, does the FDA review and audit additional tests of the cleared device after clearance? ...A. So they -- they perform routine audits of companies. Within those audits they will review a whole host of material, some of which could very well be testing of instruments. There is also a whole post market surveillance set of activities that

clearance for the surgical system "could be up to... a 10-year journey."⁷³ As summarized in the testimony of an executive at Intuitive (Glenn Vavoso), the "long development time is an outcome of various process points that you need to bring a medical device product to market that is safe for physicians to use with their patients."⁷⁴

- c. From the outset, Intuitive tested its surgical system to ensure patients realize optimal outcomes
- 32. Intuitive performs extensive testing to ensure the quality of its products, including the EndoWrist instruments, and its testing protocol has multiple facets.⁷⁵ For example, Intuitive performs live testing and statistical modeling of the EndoWrist instrument lives.⁷⁶ Intuitive set specification

the FDA conducts. And many, many times as part of those activities and interactions with companies, they'll ask for testing and data. There may be other circumstances. But those are two that come to mind.").

Vavoso (in *Rebotix*) Dep. Tr. 132:24-133:2 ("[A.] You know, what I would say is that the entire development process to achieving FDA approval, then being able to market a system -- or a system could be up to, you know, a 10-year journey.").

Vavoso (in *Rebotix*) Dep. Tr. 143:5-9 ("[A.] I think the long development time is an outcome of the various process points that you need to bring a medical device product to market that is safe for physicians to use with their patients. So I -- that's the process.").

[&]quot;Expert Report of Dr. Robert D. Howe, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, January 18, 2023 ("Howe Report"). Specifically, *see* Howe Report, § V." *See also* Intuitive-00027844.

DeSantis (in *Rebotix*) Dep. Tr. 145:9-25 ("Q. Another issue that might happen is that the EndoWrist might not have sufficient grasping force; right? A. Correct. Q. And that might happen before the lives on the use counter have run out; true? A. It -- it's possible, yes. So this is -- this is the reason we do live testing. We do live testing to be able to say things like that will not happen 95 percent of the time with 95 percent confidence. And depending on the failure mode, grasping versus cutting versus stapling versus -- we will set higher and higher specification confidence levels. And if we have a lot of things come back from the field like you're talking about that are not satisfying our requirements, we are required to do something about that."); DeSantis (in *Restore*) Dep. Tr. 22:10-23:14 ("A. ...our testing is done to a test protocol... that are developed based on product requirements and -- and risk analyses.... [the test] took [the 22 total samples] through a series of... tests that we believe would have been representative tests of what they would experience out in the field, which includes simulated surgical use and cleaning and -- and reprocessing. And then it continues to test those units, and then documents their failure at, well, whatever number; and then so the statistical method backs into how many lives that we can safely indicate based on the confidence and reliability

confidence levels, which can vary by "failure mode" (such as "grasping versus cutting versus stapling") and tests that the instruments will meet those levels.⁷⁷ Another example is that Intuitive analyzes instruments that are returned because of a customer complaint against the instrument.⁷⁸

33. When submitting documentation to the FDA for clearance, Intuitive includes its specifications and documentation (including data) that support those specifications.⁷⁹ Critically, for example,

levels that -- that you were asking me about earlier. Ours are generally 90-percent confidence and -- for some failure modes and 95 percent for others, so 95 percent reliability/90 -- 95 percent confidence and 90 percent reliability and 90 percent confidence based on the failure modes."). See also Howe Report, ¶ 70 ("... Intuitive has standard procedures for modeling the reliability of the instrument by fitting the life test data to a Weibull reliability model. ... Use of the Weibull model provides the ability to predict the reliability of the instrument as a function of number of uses, as well as uncertainty estimates (confidence intervals) for these estimates.").

- Id. See also Intuitive-00004692 at -702 ("Life testing protocols and reports trace to reliability requirements for instruments. The reliability and confidence levels of the life testing test cases vary depending on risk levels associated with different clinical risks and different failure modes."), and Intuitive-00552533, and Nixon (10/7/2022) Dep. Tr. 31:23-32:11 ("Q. And what's your general understanding of how those use limits were set? A. So for each of the instruments, there is an instrument architecture associated with it. There is a -- control parameters, how the instrument is driven, and a clinical use scenario that goes with each of the instruments, because they complete different surgical tasks. And so the combination of those three things were assessed to determine how we can ensure kind of consistent safety and efficacy of the instrument over the course of the lives of the instrument. And those came together to determine the lifes [sic] that came on the instrument.").
- DeSantis (in *Rebotix*) Dep. Tr. 203:2-7 ("Q. ... When an instrument is RMAed, that means it's experienced a failure before its use count is at zero; right? A. Perhaps. More accurately, there's some type of complaint against the instrument."); Vavoso (in *Rebotix*) Dep. Tr. 201:23-202:2 ("[A.] No, what I said was that we will receive instruments back that have had some failure or some issue and the customer has processed an RMA. And then our -- our RMA team will look at that and understand why did the instrument fail.").
- DeSantis (in *Rebotix*) Dep. Tr. 132:14-133:8 ("Q. Well, when you're submitting documentation about an EndoWrist to the FDA, you include a proposed number of lives for that instrument; right? A. Yes. Q. And then some documentation that supports that number of lives for the instrument; right? A. Yes. We -- we provide them with the specifications for the instrument, including number of lives. And then we have to prove that we're sure it will work for those number of lives, and -- and they ask for that data. ...the FDA doesn't impose specifications on -- on devices. The manufacturer will develop the specifications. And in our

for EndoWrist instruments, Intuitive includes the number of uses per instrument and provides documentation to support its specification.⁸⁰

34. In addition to the quality testing performed by Intuitive, every procedure a surgeon performs tests the integrity of the da Vinci Surgical System—including the instruments—based on the outcome of the surgeries. Since 2009, more than 9.77 million procedures have been performed with the da Vinci Surgical System worldwide. Through repeated use of the system, including the EndoWrist instruments, Intuitive continually achieves the quality objectives of the da Vinci Surgical System. Since 2009 achieves the quality objectives of the da Vinci Surgical System.

case, it's based on risk and requirements."); Rosa (in *Restore*) Dep. Tr. 42:11-43:2 ("Q. As part of [the FDA clearance] process, does Intuitive provide its own testing data for the Endowrist Instruments to the FDA? ...A. We provide extensive testing data to the FDA, yes. Q. As part of that clearance process, does Intuitive also disclose performance specifications for the Endowrist instruments to the FDA? A. I'm almost certain that our -- our requirements documents or the specifications as you're talking about them are part of that package.").

Id. See also Curet (in *Restore*) Dep. Tr. 26:17-23 ("Q. ... Does Intuitive disclose any testing data regarding any testing to determine the maximum number of lives for EndoWrist instruments to hospitals? A. We tell hospitals how many lives they can use it for and what -what -- how many lives is cleared by the FDA."). See also Johnson (in Restore) Dep. Tr. 21:23-22:10 ("...Q. Does Intuitive get clearance from the FDA for marketing and selling the EndoWrist? A. We do. Q. And that's true of the Si instruments? A. Yes. Q. And the Xi instruments? A. Yes. Q. And the instruments are all labeled with the number of lives for the instrument; is that right? A. Yes, we supply labeling that defines useful life and, often, how many times the device can be reprocessed.") and 40:16-41:8 ("Q. So Intuitive relied on simulated surgical use for its life testing? A. Yes. We're required by FDA to have our devices be tested in a simulated-use environment. They have to approximate the use environment. Q. Is that also called bench testing, or is that something different? A. It's likely something different. That's more engineering tests. Q. Do you know if there was any other life testing besides the simulated surgical uses? A. I do. We run multiple -- ... We run multiple tests, reprocessing tests, environmental tests, shipping tests, all sorts of different tests, to determine if the device is still safe and effective after it's – for its useful life.").

Intuitive 2021 Form 10-K at p. 27 ("Our success depends on the quality and reliability of our products... Because our products are designed to be used to perform complex surgical procedures, due to the serious and costly consequences of product failure, we and our customers have an increased sensitivity to such defects.").

⁸² See Public Data Workpaper.

See also DeSantis (in Rebotix) Dep. Tr. 271:6-14 ("A. Intuitive has 20 years and millions of procedures of instrument experience that -- you know, that we -- we know that what we do is

- d. Since its inception, Intuitive has employed an integrated business model
- 35. To "seamlessly translate[] the surgeon's natural hand movements... at a console into corresponding micro-movements of instruments positioned inside the patient," the da Vinci Surgical System has numerous components that must work precisely in concert. He is 1995 draft business overview, Intuitive described its system as "a combination of servo technology, specialized instruments and 3D visualization to make minimally invasive surgery more intuitive for the surgeon to perform, and more flexible with respect to the range of maneuvers the surgeon can confidently carry out." Since the launch of the first da Vinci Surgical System, Intuitive has been presenting and selling the da Vinci Surgical System as an integrated system including "a surgeon's console, a patient-side cart, a high-performance vision system, and [its] proprietary instruments."
- 36. In addition to the fact that RAS can only be carried out as the sum of the parts (i.e., with the system as a whole), a key reason why Intuitive designed its product as an integrated system is to protect "the quality and the brand and the reputation of [its] entire platform." Intuitive has a "multistep process" to terminate its relationship with customers that do not comply with its contractual agreements in order to "defend the reputation of the company and [its] platform." 88

safe, and we have a lot of information about ten lives, and quality levels, and the complaints, et cetera. So, you know, if -- I believe when we're dealing with humans, and people and patients, that the onus is on, you know, the company providing to ensure that they're safe.").

⁸⁴ Intuitive 2000 Form 10-K at p. 1.

⁸⁵ Intuitive-00595673 at -679.

⁸⁶ Intuitive 2000 Form 10-K at p. 1. See also Intuitive 2021 Form 10-K at p. 88.

DeSantis (in *Rebotix*) Dep. Tr. 265:9-11 ("A. ... We feel that defending the quality and the brand and the reputation of our entire platform is paramount to patients/people but also to the company."). *See also* DeSantis (in *Rebotix*) Dep. Tr. 279:6-9 ("A. Intuitive doesn't want anybody to adulterate our platform in any way that can't be assured that it's a sufficient quality level that we have -- that -- that we provide our sales.").

DeSantis (in *Rebotix*) Dep. Tr. 268:22-269:3 ("A. We laid out a multistep process that would eventually get to the point where we didn't want to get to. But again, to defend the reputation of the company and our platform. Then again, if the hospital continued to use something that we felt was unauthorized, unsafe, we would terminate our relationship with the hospital.").

Intuitive's testimony indicates that the critical nature of ensuring the quality and safety of the system, particularly when patients are involved, is another reason behind its integrated model.⁸⁹

2. Intuitive competes to persuade doctors (and their patients) and hospitals to choose its product over other surgical solutions

- 37. As discussed below, RAS is one of numerous treatment options for patients and healthcare providers, and the da Vinci Surgical System consistently competes with alternative surgical techniques and treatment options.
- 38. The medical community recognizes RAS as a treatment option alongside other surgical techniques. As of April 2021, there were hundreds of articles in databases of medical studies (PubMed, EMBASE, Scopus, and Cochrane Central Register of Controlled Trials) that compare RAS with laparoscopy, open surgery, or both types of surgeries based on the results of a randomized controlled trial. 90 The FDA website informs patients that "[r]obotically-assisted surgery is an important treatment option but may not be appropriate in all situations. Talk to your physician about the risks and benefits of robotically-assisted surgeries, as well as the risks and benefits of other treatment options." Medical centers, such as the Mayo Clinic, describe RAS as an alternative to other surgical techniques. 92 RAS, and the da Vinci Surgical System, is

See fn. 83 above. See also DeSantis (in Rebotix) Dep. Tr. 253:1-4 ("A. ...Because when it comes to robotic surgery, the trust and quality level to use the platform is paramount. And if you don't have that, it could destabilize the entire platform.").

Naila H. Dhanani et al., "The Evidence Behind Robot-Assisted Abdominopelvic Surgery: A Systematic Review," *Annals of Internal Medicine* 174, No. 8 (2021): 1-2 ("Dhanani et al.").

[&]quot;Computer-Assisted Surgical Systems," U.S. Food and Drug Administration, accessed January 16, 2023, https://www.fda.gov/medical-devices/surgery-devices/computer-assistedsurgical-systems.

[&]quot;Robotic Surgery," Mayo Clinic, accessed January 12, 2023, https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974 ("Surgeons who use the robotic system find that for many procedures it enhances precision, flexibility and control during the operation and allows them to better see the site, compared with traditional techniques.").

frequently compared with open surgery, laparoscopic surgery, and alternative options when deciding on the appropriate treatment for a patient.⁹³

39. Evidence shows that healthcare providers consider costs when assessing their options across surgical solutions. For example, Intuitive's Customer Finance and Market Intelligence teams collaborated to develop a survey for approximately 600 customers within Intuitive's customer finance portfolio. 94 According to Intuitive, one of the key findings from the survey is that strategic, budgetary and return-on-investment opportunities all influence capital acquisition timelines for hospitals. 95 Testimony from hospital administrators about how they make capital allocation decisions confirms this. For example, Paul Plomin, vice president of finance for Franciscan Alliance, 96 acknowledges that their estimates of potential revenue from a capital expenditure take into account procedure volumes, service lines, and pay mix, among other things. 97 Similarly, they consider both the initial costs of capital as well as ongoing costs related to servicing or instruments and accessories. 98 Capital limitations are cited as the top reason for leasing as opposed to buying a surgical solution such as Intuitive's. 99

In addition, a number of health insurers, including the Center for Medicare and Medicaid Services ("CMS"), pay the same reimbursement for da Vinci surgeries as for laparoscopic surgeries. *See* "Reimbursement Resources," Intuitive Surgical, Inc., accessed January 5, 2023, https://www.intuitive.com/en-us/about-us/company/reimbursement ("Surgical procedures performed using robotic assistance should be billed using existing CPT codes for laparoscopic surgical procedures when available."). *See also* "Da Vinci Surgical System 2022 U.S. Coding and Reimbursement Guide," Intuitive Surgical, Inc., accessed January 16, 2023, https://www.intuitive.com/en-us/-/media/Project/Intuitive-surgical/files/pdf/intuitive-da-vinci-reimbursement-and-coding-guide-1086609.pdf?la=en&hash=8165652F394F52049A8C6B333AFACDA8.

⁹⁴ See Intuitive-00045861 at -864.

⁹⁵ Intuitive-00045861 at -875.

Plomin (11/8/2022) Dep. Tr. 14:13-15 ("Q. What is your role at Franciscan? A. Vice president of finance for Franciscan Alliance.").

⁹⁷ Plomin (11/8/2022) Dep. Tr. 60:10-62:20 and 65:10-66:5.

Plomin (11/8/2022) Dep. Tr. 63:17-64:7. See also Plomin (11/8/2022) Dep. Tr. Exhibit 188B, which is a capital acquisition request form for three da Vinci Xi systems and details the financial considerations for the potential acquisition.

⁹⁹ Intuitive-00045861 at -872.

- 40. In addition to cost considerations, evidence indicates that hospital administrators also consider patient safety and outcomes when choosing a surgical solution. In an Intuitive presentation showing results from a hospital decision maker survey, hospital respondents consistently identified patient safety and satisfaction as an important component when demonstrating the need for large capital expenditures like surgical solutions. ¹⁰⁰ For example, Paul Plomin of Franciscan Alliance emphasizes that safety is their first priority in making capital allocation decisions. ¹⁰¹ Patient need is one of the top drivers for upgrading to newer technology but when hospitals have competing capital expenditure priorities, return-on-investment determines investment in a surgical solution. ¹⁰²
- 41. Evidence also indicates that surgeons compared da Vinci and laparoscopy in the context of deciding whether to acquire a da Vinci Surgical System. For example, when Valley Medical Center was considering whether to purchase a second da Vinci Xi System, Dr. Landers wrote, "I was certainly hoping to move forward with Xi robot cases much sooner than I anticipated given the great advantages for surgeon and patients versus laparoscopic approach." ¹⁰³
- 42. Intuitive publicly compares the da Vinci Surgical System to alternative surgical solutions and treatments. In its public filings, Intuitive notes that it faces competition "with established minimally invasive surgery and open surgery" that are "widely accepted in the medical community and in many cases have a long history of use." ¹⁰⁴ The presence of these alternative options is also reflected in Intuitive's marketing materials, where Intuitive has developed tools based on clinical and economic data comparing the value of RAS versus laparoscopic versus

¹⁰⁰ Intuitive-00118636 at -647.

Plomin (11/8/2022) Dep. Tr. 32:13-19 ("Q. How are individual Franciscan facilities expected to prioritize or rank their -- their requests on an annual basis? A. Well, number one should be if we have any safety issues. In fact, if it's a safety issue, we'll allocate the capital currently. We wouldn't wait for the next year.").

¹⁰² Intuitive-00045861 at -876.

¹⁰³ VMC-00014375 at -379.

¹⁰⁴ Intuitive 2000 Form 10-K at p. 31. See also Intuitive 2021 Form 10-K at p. 25.

open surgery for both patients and hospitals. ¹⁰⁵ In these calculations, Intuitive appears to aim to demonstrate to healthcare providers as well as surgeons that the benefit of da Vinci surgeries—inclusive of savings related to improved patient outcomes—can translate to economic value. ¹⁰⁶

D. THE HISTORY OF SIS AND ITS ENDOWRIST RESET SERVICE

43. Below, I provide a brief history of SIS and its role as a distributor of Rebotix Repair LLC ("Rebotix")'s Interceptor "technology" to bypass the usage limits on the EndoWrist instruments as specified by Intuitive.

1. SIS has been maintaining, repairing, and replacing medical equipment and continues to perform these activities

44. SIS is a surgical instrument and device repair company that was founded in 1971. SIS provides repairs for a variety of instruments including stainless steel instruments and specialty surgical instruments such as flexible endoscopes, video systems, and orthopedic drill saws. 108

¹⁰⁵ Intuitive-00412740 at -746 through -755.

Intuitive works with hospitals to measure specific clinical outcomes (including the rate of complications and the number of times a surgery must be "converted" to open surgery because of complications arising from the robotic surgery process) associated with the da Vinci surgeries performed by that hospital. *See*, e.g., Intuitive-00038260 at -266 through -277.

See, e.g., Intuitive-00001788 at -815, -816 and Intuitive-00001237 at -272 ("[W]hen you look beyond supply costs and consider the potential improvement in outcomes, the impact of the total cost to treat patients can represent significant cost savings to hospitals.").

¹⁰⁷ "About Us," Surgical Instrument Service Company, accessed January 3, 2023, https://sis-usa.com/about/.

Posdal (in *Restore*) Dep. Tr. 6:20-7:1 ("Q. What sorts of devices does S.I.S. repair? A. A wide breadth of services from general stainless steel type instruments, scissors, hemostats and the like, to specialty surgical instruments to rigid endoscopes, flexible endoscopes, video systems, orthopedic drill saws, reamers, and some other miscellaneous items."). *See also* Posdal (in *Restore*) Dep. Tr. 70:18-25 ("Q. What are some of the other instruments that S.I.S. repairs? A. General surgery instruments; specialty surgery instruments, mostly stainless steels; bipolar instruments; monopolar instruments, that's electrosurgery; instruments -- flexible endoscopes; rigid endoscopes; power equipment; video equipment; and some other

SIS's annual gross revenue for 2019 and 2020 was \$7 and \$10.7 million, respectively. ¹⁰⁹ Greg Posdal is SIS's current president and CEO and served in those positions for approximately 20 years. ¹¹⁰

45. About 85 percent of SIS's business is from acute care hospitals and medical centers and the other 15 percent is with outpatient clinics, Ambulatory Surgical Centers, or non-acute centers. 111

2. SIS's sales of Si EndoWrist instruments resets as a distributor for Rebotix Repair

46. SIS learned of EndoWrist resetting through Rebotix Repair ("Rebotix"), a privately held company that focuses on resetting the number of uses of EndoWrist instruments for the da Vinci S/Si systems by using Rebotix's Interceptor chip to bypass the instruments' usage limits. 112 As part of its efforts to reach and engage with customers, Rebotix worked with distributors and sales

miscellaneous items."); "Services," Surgical Instrument Service Company, accessed January 3, 2023, https://sis-usa.com/services/.

¹⁰⁹ SIS320176 at -176 and SIS320922 at -922.

¹¹⁰ Posdal (in *Restore*) Dep. Tr. 27:5-6 ("Q. What is your current position? A. President, C.E.O.").

¹¹¹ Johnson 30(b)(1) (10/27/2022) Dep. Tr. 14:12-18.

Posdal (in *Restore*) Dep. Tr. 31:11-32:11 ("Q. When did you first have contact with Rebotix Repair? A. Summer of 2019, June-ish. Q. And was there anyone who was involved in connecting you with Rebotix Repair? A. I was working with Chris Gibson, who was supplying us with camera parts. And they were starting this other business, Rebotix, and that's how I found out about them. Q. Do you have any understanding that Rebotix Repair had done any work on EndoWrist instruments prior to it being formed as Rebotix Repair? A. No. Q. What was your basis of your understanding that Rebotix was starting a business? A. A conversation with Chris Gibson. Q. And did Mr. Gibson inform you that Rebotix Repair was starting a new business? A. That they already had, yes. Q. And what was that business? A. Basically, gathering EndoWrists that were near their expiration, number of uses, and being able to reprogram the chip so that the com – the robot would read additional use availability, and making any other adjustments that needed to be to bring it back within spec if it was out of spec."). *See also* Papit (in *Rebotix*) Dep. Tr 100:5-8 ("Q. You said earlier that the Interceptor usage counter reset is only available for the EndoWrist for the S and Si da Vincis; is that right? A. Yes.").

representatives. ¹¹³ As compensation, distributors and sales representatives received the difference between the retail price to the customer and the "distributor price" or "sales rep. price" set by Rebotix. ¹¹⁴ In the summer of 2019, Mr. Posdal spoke with Chris Gibson, COO at Rebotix, ¹¹⁵ about Rebotix's business proposition to gather EndoWrists near expiration and reprogram them for additional uses. ¹¹⁶ SIS previously worked with Benjamin Biomedical, a "medical instrument repair services" company that shares employees with Rebotix, including

Papit (in *Rebotix*) Dep. Tr. 102:19-21 ("Q. Did Rebotix use distributors to sell its service offerings on EndoWrist instruments? A. Yes."). *See also* Papit (in *Rebotix*) Dep. Tr. 152:17-20 ("Q. Were -- does Rebotix work with any sales representatives? A. Yes, we work with several independent sales representatives."); Papit (in *Rebotix*) Dep. Tr. 153:6-13 ("Q. Were the sales representatives' responsibility similar to distributors? A. That was just about identical. They would perform the same function basically. Q. Was there anything different about the sales representatives' function as compared to the distributors? A. Not really, no.").

REBOTIX062113 and REBOTIX056093 ("Sales Rep Pricing.docx"); REBOTIX040273 and REBOTIX040277 ("Rebotix Distributor Pricing.xlsx"); REBOTIX175326. *See also* SIS070889 and SIS071311.

¹¹⁵ Gibson (in *Rebotix*) Dep. Tr. 73:8-12 ("Q. Are you currently employed by Rebotix Repair LLC? A. Yes. Q. What's your title? A. COO.").

Posdal (in *Restore*) Dep. Tr. 32:2-11 ("Q. And did Mr. Gibson inform you that Rebotix Repair was starting a new business? A. That they already had, yes. Q. And what was that business? A. Basically, gathering EndoWrists that were near their expiration, number of uses, and being able to reprogram the chip so that the com -- the robot would read additional use availability, and making any other adjustments that needed to be to bring it back within spec if it was out of spec."). *See also* Posdal (in *Restore*) Dep. Tr. 50:2-12 ("Q. And how did the issue come up in that relationship with Rebotix about, quote, repairing, end quote, EndoWrist instruments? A. I ran into them at an industry trade show in Cleveland. I can't remember the exact show. It may have been IACSMM, which is Central Sterile Materiel Management -- materiel managers [sic]. It was Cleveland late spring, early summer 2019. And he was there, I didn't know he was going to be there, but he was there with -- promoting this process.").

Chris Gibson, ¹¹⁷ because Benjamin Biomedical sells SIS's components for video equipment repair. ¹¹⁸

- 47. SIS entered into a relationship with Rebotix in June 2019 for the reset of da Vinci instruments. 119 SIS served as a Service Center and distributor for Rebotix according to draft agreements. 120
- 48. According to Mr. Posdal, SIS did not perform any of the EndoWrist instrument resets in house. SIS picked up the instruments from hospitals and sent the instruments to Rebotix, who performed the resets. 121 SIS did not independently verify Rebotix's claims that the Rebotix reset

[&]quot;Certified Surgical Instrument Repair Services," Benjamin Biomedical, accessed January 5, 2023, https://benjaminbiomedical.com/; Papit (in *Rebotix*) Dep. Tr. 32:13-21 ("Q. Do Benjamin Biomedical and Rebotix Repair share any employees? A. Yes. Q. Who are those employees? A. Greg Fiegel does services for both, Chris Gibson does services for both, and I do services for both, and there are several technicians -- I shouldn't say several. There's one or two technicians who are cross-trained."); and BB001260 ("Benjamin Biomedical, Inc. Employee List").

Posdal 30(b)(1) (11/1/2022) Dep. Tr. 23:23-24:3 ("[A.] ... As – as stated earlier, we had a long lasting relationship with Benjamin Biomedical, which has the same – same individuals involved with it as re – as Rebotix. And I had seen them at one of the trade shows we were at, and they were displaying that new technology."). *See also* Posdal (in *Restore*) Dep. Tr. 49:21-50:1 ("Q. Okay. Let me try to shortcut some of the questions I had before the break. Mr. Posdal, how were you first introduced to Rebotix Repair? A. We were working on another project together. They sell our company components for video equipment repair.").

¹¹⁹ Posdal (in *Restore*) Dep. Tr. 31:11-13 ("Q. When did you first have contact with Rebotix Repair? A. Summer of 2019, June-ish.").

SIS000046 and SIS000035 ("SIS Rebotix Distributor Agreement"). I understand that there was no formally signed agreement between Rebotix and SIS but there are draft agreements. Posdal 30(b)(1) (11/1/2022) Dep. Tr. 41:23 – 42:5 ("Q. Did SIS and Rebotix ever have a written agreement? A. We were in the process of that. Again, ...this all got shut down so quickly that things just got put on the back burner. So there was an agreement written. I don't believe there was an agreement signed. But there is a -- a verbal understanding that -- that we would continue.").

Posdal (in *Restore*) Dep. Tr. 31:7 -10 ("Q. That's the company Rebotix Repair? A. Yep. And they actually performed the work for us. We picked it [instrument] up, sent it to them, and they did the repairs."). *See also* Johnson 30(b)(6) (10/27/2022) Dep. Tr. 92:12-93:23 ("Q. Does SIS have the capability to perform any repairs or services on the da Vinci robot itself? A. No.").

process did not impact patient safety, that Rebotix did not need the original specifications from Intuitive to reset da Vinci instruments, and that the limit on the number of uses was arbitrary. 122

- 49. Between June 2019 and December 2019, SIS served as a distributor for Rebotix Repair. 123

 During this period, SIS sold approximately 41 reset EndoWrist instruments. 124 According to Mr.

 Johnson, SIS charged customers 70 to 80 percent of the price of a new EndoWrist for the reset EndoWrist. 125 SIS's last recorded sale of an EndoWrist reset is dated December 10, 2019. 126
- 50. SIS signed an agreement and amendment with Vizient to provide da Vinci instrument reset services to Vizient members. ¹²⁷ In addition to da Vinci instrument reset services, SIS also provided repairs for rigid endoscopes, video cameras, laparoscopic and bipolar instrumentation,

¹²² Posdal (in *Restore*) Dep. Tr. 41:6-45:6; Johnson 30(b)(6) (10/27/2022) Dep. Tr. 31:10-32:4.

Posdal (in *Restore*) Dep. Tr. 31:7-10. ("Q. That's the company Rebotix Repair? A. Yep. And they actually performed the work for us. We picked it up, sent it to them, and they did the repairs."); Posdal (in *Restore*) Dep. Tr. 54:1-4 and SIS000046 [Posdal (in *Restore*) Dep. Tr. Exhibit 4]. *See also* SIS048254 (cover email for "davinci.xlsx") and SIS048255 ("davinci.xlsx"). Although this file includes other transactions, I understand from SIS's testimony that the only EndoWrist usage-counter reset transactions are those dated between June 28, 2019 (for Legacy Good Samaritan), and December 10, 2019. *See also* Posdal 30(b)(1) (11/1/2022) Dep. Tr. 89:7-18 ("Q. Does that time period, roughly April 2020, sound like when SIS's EndoWrist repair business was shut down? Does that timing seem right to you? ... [A.] Let me think. Likely before that. I think what we see after about 12/10 -- or 12/18 were endoscopes, and I'm not sure that the CPE entry is even a -- an Intuitive device. Not sure how it's on there. It's listed as a cautery hook. I don't believe that is a -- is an EndoWrist device. It seems like it would be, if I had to guess, closer to December of 2019.").

SIS048255. *See also* SIS000097. According to SIS invoices, the earliest da Vinci EndoWrist instrument reset occurred on June 28, 2019.

Johnson 30(b)(6) (10/27/2022) Dep. Tr. 36:14-16. ("Q: Okay. So -- so the customer would pay between 70 and 80 percent of what a new EndoWrist would cost from Intuitive; is that right? A: Correct.").

¹²⁶ SIS000167.

¹²⁷ SIS000051. See also SIS000047 (Amendment to SIS Vizient Agreement).

Olympus ultrasound endoscopes, and other medical equipment through Vizient to its member hospitals. 128

III. THE DA VINCI SURGICAL SYSTEM IS A SINGULAR PRODUCT FOCUSED ON OPTIMIZING PATIENT SAFETY AND OUTCOMES

- 51. Dr. Lamb's opinions concerning asserted anticompetitive harm depend on the existence of distinct markets for "minimally invasive soft tissue surgical robots" (or "MIST Surgical Robots") and a distinct "aftermarket" for "replacements and repairs of EndoWrists" (or "EndoWrist Repair and Replacement"). 129 This is because Dr. Lamb posits a tying theory based on a forced or coerced relationship between products in these two putative markets. Namely, Dr. Lamb claims that Intuitive "used its monopoly power in the market for MIST Surgical Robots to maintain its monopoly in the EndoWrist Repair and Replacement Market in the U.S. during the Relevant Period" and that Intuitive's alleged misconduct "resulted in harm to competition." 130
- 52. Dr. Lamb claims that the market for "MIST Surgical Robots"¹³¹ and the market for "EndoWrist Repair and Replacement"¹³² are distinct relevant antitrust product markets, ¹³³ offering two reasons in support of these claims. First, Dr. Lamb asserts that "hospital demand for EndoWrist surgical instruments is separate and distinct from demand for da Vinci surgical robots."¹³⁴ To support this claim, Dr. Lamb asserts that (i) the timing and nature of purchasing decisions may vary between the "robots" and EndoWrist instruments, ¹³⁵ (ii) purchases of EndoWrist

SIS001981. See also Johnson 30(b)(6) (10/27/2022) Dep. Tr. 93:24-94:2 ("Q. Does SIS offer any services related to the robotic endoscopes? A. We have repaired rigid endoscopes from Intuitive for customers in the past, yes.").

¹²⁹ Lamb Report, ¶ 4.

¹³⁰ Lamb Report, \P 9.

¹³¹ Lamb Report, ¶ 4.

¹³² *Id*.

¹³³ Lamb Report, ¶ 9.

Lamb Report, \P 71.

¹³⁵ Lamb Report, ¶¶ 71, 75-76.

instruments vary based on the "types of surgeries typically performed at a given hospital," ¹³⁶ and (iii) the "[r]obots" and EndoWrist instruments are "not typically sold in fixed proportions." ¹³⁷ Second, Dr. Lamb claims that Intuitive itself views robotic platforms and instruments as distinct products. ¹³⁸ Specifically, Dr. Lamb cites to Intuitive's 2021 Form 10-K filing in which Intuitive reports separate descriptions and revenue streams for (i) da Vinci platforms and (ii) instruments and accessories. ¹³⁹

- 53. A threshold issue in the assessment of Dr. Lamb's opinions is whether, economically, Intuitive's surgical system as a whole should be considered a singular product that includes a platform and component parts, including EndoWrist instruments. As described in detail below, Intuitive's surgical system should be viewed as a singular economic product for several related reasons:
 - a. As a threshold matter, both by design and performance, the Intuitive system is composed of interdependent complements in terms of product reliability and, in turn, Intuitive's reputation with doctors, patients, and healthcare providers (Section A). As I explain in greater detail in Section VII below, this interdependence among the components of the da Vinci Surgical System presents a situation where, because of economic efficiency and the avoidance of harmful negative externalities such as free-riding by third parties and customers, it is natural and optimal for the da Vinci Surgical System to be sold as a singular product.
 - b. Intuitive designed the da Vinci Surgical System with a "product vision"¹⁴⁰ that can only be achieved by the system as a whole (Section B). Components of the system (such as the da Vinci platform and EndoWrist instruments) are integral to the functioning of the system. Moreover, many of the components (including the EndoWrist instruments at issue) only are used with the da Vinci Surgical System, and the da Vinci Surgical System only uses components that have been manufactured or authorized by Intuitive.

¹³⁶ Lamb Report, ¶ 71.

¹³⁷ Lamb Report, ¶ 73.

¹³⁸ Lamb Report, ¶¶ 74-75.

¹³⁹ Id

¹⁴⁰ Intuitive-00270554 at -559. *See also* Azizian et al. at p. 9.

- c. From the outset, Intuitive has sold the da Vinci Surgical System as an integrated product (Section C). Moreover, in its public statements and customer contracts, Intuitive has been transparent about the expected lifetime costs associated with the system, which include the capital cost of the da Vinci platform and ongoing costs of the instruments. Although the lifetime costs vary across customers depending on their surgical volumes and procedure categories (e.g., hysterectomies and cholecystectomies), customers are apprised from the outset that they are purchasing a system with costs spread over time.
 - i. Intuitive designed the very first da Vinci Surgical System to be sold as an integrated product.
 - ii. Intuitive continuously has been selling the da Vinci Surgical System as an integrated product while innovating on various components.
- d. Other manufacturers of RAS systems, faced with similar product complementarities and potential for negative externalities, also sell their systems as an integrated product (Section D).
- 54. These economic factors and marketplace facts provide strong evidence that, as a matter of economics, the da Vinci Surgical System should be considered as a singular product.
 - A. AS CRITICAL COMPLEMENTS IN QUALITY AND RELIABILITY, THE COMPONENTS OF INTUITIVE'S ROBOTIC SURGICAL SYSTEM ARE PROPERLY VIEWED AS A SINGLE PRODUCT
- 55. A threshold economic question is whether the economic conditions here make it more appropriate to consider Intuitive's surgical system as a singular product rather than the distinct products asserted by Dr. Lamb. ¹⁴¹ To assess this issue at the conceptual level, I first consider (i) whether, due to strong complementarity among its components, it is economically efficient for the da Vinci Surgical System to be sold as a singular product, and (ii) whether there are negative externalities attendant to the sale of Intuitive's system and components (particularly EndoWrist instruments) that further discourage Intuitive from allowing separate sales (by other companies)

¹⁴¹ Lamb Report, § IV.C.

of components of the da Vinci Surgical System. Here, both factors strongly support the conclusion that Intuitive's surgical system is one product that is sold over time in a surgical solutions marketplace.

1. The da Vinci platform and its components are complements in the provision of surgical services

- 56. There is little room to dispute that the da Vinci platform and its instruments are complements in reliability and quality and, hence, both contribute critically to the reputation of da Vinci Surgical Systems. ¹⁴² In fact, a review of the factual record confirms that, from the outset, the component parts of the da Vinci Surgical System have been integral to the system's performance and reputation. ¹⁴³ Hence, as a matter of economics, the da Vinci Surgical System is properly considered a singular product, notwithstanding that sales of instruments occur over time. On the contrary, the reputational complementarity and interdependence exist at all times and remain critical to Intuitive's success as it continues to innovate in the surgical solutions marketplace.
- 57. As I explain in Section VII, when there is strong complementarity among a product's components, even though the components could be sold separately, it is economically most efficient to always sell them together, as has been the case with the da Vinci Surgical System. In such situations, keeping the components of the product together can reduce costs and improve quality for consumers.

DeSantis (in *Rebotix*) Dep. Tr. 253:1-4 ("A. ...Because when it comes to robotic surgery, the trust and quality level to use the platform is paramount. And if you don't have that, it could destabilize the entire platform.").

It is my understanding that all components (including the da Vinci platform and EndoWrist instruments) are integral to the function of the da Vinci Surgical System. *See* Section III.B below for further discussion.

¹⁴³ *See* ¶ 35 above.

- 2. There are obvious and significant negative externalities associated with any non-controlled third-party sale of replacement instruments
- 58. In economics, a negative externality is a cost or negative effect foisted by one party on another, when the responsible party does not bear the full consequences of those actions. ¹⁴⁴ Here, the potential for negative externalities from third-party instrument resets is obvious and arises from two related sources. First, third-party reset providers, such as SIS, do not share the same interest in protecting the quality and reputation of da Vinci Surgical Systems throughout the marketplace and into the future. ¹⁴⁵ On the contrary, SIS has a narrow interest in selling reset instruments to various hospitals, and because Intuitive is the original equipment manufacturer ("OEM") of the da Vinci Surgical System, the effects of any quality failures likely will fall primarily on Intuitive rather than SIS. ¹⁴⁶ This is particularly true here, where SIS advertised the interchangeably of its EndoWrist resets with Intuitive's brand-new EndoWrist instruments, writing, "A repaired EndoWrist is not an alternative or replacement device. It is an original da Vinci manufactured device that has been repaired to [its] original specifications." ¹⁴⁷ Second, and to lesser extent,

¹⁴⁴ Pindyck and Rubinfeld at pp. 661-662.

Third parties such as SIS have incentives to protect their own reputation that are not necessarily aligned with Intuitive's business interests (or are not aligned to the same degree as Intuitive). Some reasons are: (1) third parties do not have as much at stake if something goes wrong as Intuitive does; (2) third parties can hurt Intuitive's reputation without harming their own interest by shifting blame for malfunctions on the OEM (i.e., Intuitive); and (3) third parties including SIS easily can redeploy their resources to do work on medical equipment repairs for other manufacturers.

Because SIS acted as a distributor for Rebotix rather than resetting the EndoWrist instruments themselves, the factors that make Rebotix unlikely to bear the consequences of a quality failure also apply to SIS. In the past, Rebotix has claimed "intentionally inflicted damage" as a probable reason for instrument failure following a third-party "repair" (Papit (in *Rebotix*) Dep. Tr. Exhibit 10 and Restore-00003932). Moreover, if an entity is remanufacturing the original manufacturer's devices without complying with the FDA's requirements for manufacturers, including reporting requirements, then any adverse events associated with the remanufactured instrument would only appear as associated with the original manufacturer (Expert Report of Christy Foreman, MBE, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, January 18, 2023, ¶ 190).

¹⁴⁷ SIS001684.

there are some hospitals that likewise seek to pursue perceived short-term cost savings with purchases of instrument resets from SIS, but again without regard to the broader consequences that likely would befall Intuitive in the marketplace should those instruments fail or perform poorly in particular instances. ¹⁴⁸ In economics, these are classic examples of quality/reputation externalities present here from the outset of Intuitive's entry into the marketplace.

- 59. These externalities would be less important, of course, if both or one of the component parts of the system were not important to the overall quality and performance of the system—i.e., if the products were not complements. If, for example, the component part at issue does not contribute to the reputation of the producer's overall system, one could see how the independent commoditization of that component may not generate externalities that warrant singular product treatment. In contrast, here, the complementarity and negative externality rationales for Intuitive's marketing its surgical system as a singular product reinforce one another.
 - B. INTUITIVE DESIGNED THE DA VINCI SURGICAL SYSTEM BASED ON FOUR "PRODUCT PILLARS" THAT ONLY CAN BE ACHIEVED BY THE SYSTEM AS A WHOLE
- 60. When Intuitive started to develop the da Vinci Surgical System in 1995, it designed the system as an integrated product rather than "distinct" products. Specifically, Intuitive's "product vision" of the da Vinci Surgical System had "four key specifications, or product pillars." The pillars are:
 - a. "[f]irst and foremost, the system needed to be reliable and failsafe in order to be feasible as a surgical device;"
 - b. "the system was to provide the user with intuitive control of the instrument;"

Although hospitals also need to protect their reputations for patient safety, they are able to continue performing other types of surgeries whereas Intuitive's business is primarily focused on the da Vinci Surgical System (Intuitive 2021 Form 10-K at p. 6-7).

¹⁴⁹ Intuitive-00270554 at -559.

- c. "the instrument tips were to have six-degree-of-freedom dexterity as well as a functional gripper;" and
- d. the system needed to have "compelling 3D vision." ¹⁵⁰
- 61. Critically, it is my understanding that the components of the da Vinci Surgical System (such as the da Vinci platform and EndoWrist instruments) are integral to the functioning of the system that supports the "product pillars."
 - a. For the system to be "reliable and failsafe," ¹⁵¹ all components are required to meet stringent safety standards and to communicate with the system seamlessly. The safety standards are set by regulatory bodies (such as the FDA, Japanese Ministry of Health, Labor, and Welfare, and EU). ¹⁵² In addition to government regulations, Intuitive conducts its own tests of safety and reliability. ¹⁵³
 - b. To achieve "intuitive" control of the instrument, the surgeon console "blends visualization and instrument control." One example of a way in which the da Vinci Surgical System improves on "intuitive" control is that its hand controllers "mimic the movement of the endeffectors," similar to how a surgeon's hands may move for open surgery. In contrast, in traditional laparoscopy, the instruments move in the "opposite direction from the surgeon's

¹⁵⁰ *Id*.

¹⁵¹ *Id*.

¹⁵² Intuitive 2021 Form 10-K at pp. 14-18.

¹⁵³ See, e.g., Howe Report, § V.B ("Intuitive Designs and Tests its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of 'Lives'").

¹⁵⁴ Azizian et al. at p. 9 (Figure 4).

¹⁵⁵ Sally Kathryn Longmore et al., "Laparoscopic Robotic Surgery: Current Perspective and Future Directions," *Robotics* 9, No. 2 (2020): 6 ("Longmore et al.").

Although some robotic assisted surgical systems use "similar hand control interfaces" as the da Vinci Surgical System, other systems choose to imitate the movements of traditional laparoscopic surgery. TransEnterix's Senhance System is an example of the latter. *See* Longmore et al. at p. 6.

- hands."¹⁵⁷ The da Vinci Surgical System translates the movements by the surgeon at the surgeon console to the instruments, which are attached to the arms of the patient cart. ¹⁵⁸
- c. The "dexterity" of the EndoWrist instruments is a signature attribute of the da Vinci Surgical System. ¹⁵⁹ This dexterity is made possible through a cable and pulley system. ¹⁶⁰ Some of the "degrees of freedom" are found at the end of the instrument (such as "[f]lexion and extension," "abduction and adduction," and "open[ing] and closing"), and others are driven by the robotic arm that is attached to the patient cart ("in and out, pitch, yaw and rotation"). ¹⁶¹
- d. For 3D vision, the system uses a custom-designed 162 stereoscopic endoscope (which Intuitive categorizes as an accessory of the system), 163 fluorescence imaging, and vision cart (which is part of the da Vinci platform). 164

¹⁵⁷ Intuitive 2000 Form 10-K at p. 3.

Azizian et al. at p. 8 ("The computerized control system extends the surgeon's 'presence' – their sensory awareness and control – into the surgical field by transmitting video images from the endoscopic camera to the stereo viewer of the console, and transmitting the surgeon's hand motions – measured by the master interfaces – to the slave manipulators. Since this is an electronic link, the software of the control system can modify the signals, so as to filter out the surgeon's normal physiological tremor, or to scale down their motions for enhanced precision.").

[&]quot;Da Vinci Instruments – Trusted dexterity," Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/products-and-services/da-vinci/instruments. See also Azizian et al. at p. 15 ("Many of these instruments have an articulated wrist mechanism to allow for dexterous and intuitive tissue interaction, following the surgeon's wrist articulation while controlling motion from the master interfaces of the surgeon console."). See also

Howe Report, \P 30.

¹⁶¹ Longmore et al. at p. 14.

Earlier prototypes of the da Vinci Surgical System used stereo endoscopes produced by Welch Allyn and Olympus, and the endoscope on the final da Vinci Surgical System has "dual optical trains and dual three-chip camera heads" (whereas other endoscopes have a single optical train or two video chips). *See* Intuitive-00270554 at -560-561.

Intuitive 2021 Form 10-K at p. 8 ("Accessory products include sterile drapes used to help ensure a sterile field during surgery, vision products, such as replacement 3D stereo endoscopes, camera heads, and light guides, and other items that facilitate use of the da Vinci Surgical Systems.").

¹⁶⁴ Azizian et al. at pp. 12-13.

- 62. In fact, Dr. Lamb's expert report highlights many of these advantages of the da Vinci Surgical System. 165 For example, Dr. Lamb cites to the testimony of a third-party hospital representative who identified "greater dexterity, better visualization, easier access to areas inside a body cavity that are difficult to access with traditional laparoscopic instruments" as benefits of da Vinci surgery over traditional laparoscopic surgery. 166 Moreover, according to another third-party hospital representative, da Vinci surgery yielded "less pain, less scarring, a shorter hospital stay, and a quicker return to their daily activities" for patients. 167 Evidence indicates that these benefits are only possible as the sum of the components, including the precision of the instruments created by Intuitive for the system. 168
- 63. Further, until 2019, Intuitive's product portfolio centered on the da Vinci Surgical System, and the da Vinci Surgical System continues to be the company's primary system for surgery. 169 And,

¹⁶⁵ Lamb Report, ¶¶ 35-39.

¹⁶⁶ Lamb Report, ¶ 36 (citing to Donovan (5/27/2021) Dep. Tr. 18:22-19:11).

¹⁶⁷ Lamb Report, ¶ 36 (citing to Harrich (5/24/2021) Dep. Tr. 17:11-20:22). See also

¹⁶⁸ See, e.g., Intuitive 2021 Form 10-K at p. 7 ("With our technology, a surgeon can also use 'motion scaling,' a feature that translates, for example, a three-millimeter hand movement outside the patient's body into a one-millimeter instrument movement in the surgical field inside the patient's body. Motion scaling is designed to allow precision and control for delicate tasks."). See also DeSantis (in Rebotix) Dep. Tr. 107:14-25 ("Q. ...Intuitive markets robotic instruments as having some advantages over traditional laparoscopic surgery; right? A. The -- the overall surgical platform has advantages over laparoscopic instruments, yes. Q. When you mentioned 'the overall surgical platform,' that includes the actual robot that's performing surgery on the patient; right? A. Yes. Q. Includes the surgeon console at which the surgeon sits during the procedure; right? A. Yes."); DeSantis (in *Rebotix*) Dep. Tr. 109:1-3 ("A. ...my words would be greater precision, control, ergonomics are all benefits associated with the da Vinci platform."); Lamb Report, ¶ 15 ("Robotic surgery provides a number of benefits to both patients and surgeons as compared to traditional laparoscopic surgeries. For the patient, these benefits include a more precise surgery, significantly less pain, less risk of infection and blood loss, earlier discharge from the hospital, less scarring and shorter recovery, and, in many cases, better clinical outcomes. For the surgeon, these benefits include an enhanced visual field, superior dexterity, and access to hard-to-reach places.").

In 2019, Intuitive introduced the Ion endoluminal system for "minimally invasive peripheral lung biopsy." "Ion by Intuitive," Intuitive Surgical, Inc., accessed January 12, 2023, https://www.intuitive.com/en-us/products-and-services/ion. See also Intuitive Surgical, Inc.

in all instances, the da Vinci Surgical System uses components that are either manufactured or carefully controlled and authorized by Intuitive.¹⁷⁰ Intuitive does not sell parts to other medical-device manufacturers for use in other systems;¹⁷¹ the company's mission and sales are focused on its own systems.¹⁷²

64. In sum, Intuitive designed the da Vinci Surgical System as the sum of components, including the da Vinci platform (surgeon console, vision cart, and patient-side cart) and instruments and accessories where the instruments are "used interchangeably during [] surgery" depending on the needs of the specific procedure and surgeon(s).¹⁷³

Form 10-K For the Fiscal Year Ended December 31, 2019 ("Intuitive 2019 Form 10-K") at pp. 8, 46 and Intuitive 2021 Form 10-K at p. 6 ("Advanced robotic systems provide precise, powerful systems with high-performance vision extending care team's capabilities to enhance minimally invasive care. These systems include the da Vinci Surgical System, which was designed to enable complex surgery using a minimally invasive approach, and the Ion endoluminal system, which extends our commercial offerings beyond surgery into diagnostic procedures, enabling minimally invasive biopsies in the lung.").

DeSantis (in *Rebotix*) Dep. Tr. 23:23-24:4 ("Q. ...Is it your understanding that Intuitive designed the da Vinci robots to only function with instruments that are produced by Intuitive? A. Yes. Q. And that was an intentional design decision; right? A. Absolutely."). *See also* DeSantis (in *Rebotix*) Dep. Tr. 87:9-18 ("Q. Now, when did Intuitive first develop the EndoWrist device for use with the da Vinci surgical platform? A. That was way before my time with the company. It was certainly a core feature of the da Vinci platform, so I would say it goes way back to the beginnings of the company. Q. When you say 'the beginnings of the company," do you have a general timing sense of when that was? A. In the late '90s, 1990s.').

¹⁷¹ See Intuitive 2021 Form 10-K at pp. 6-8 for a list of all Intuitive products.

¹⁷² Intuitive 2021 Form 10-K at p. 6 ("Intuitive is committed to advancing minimally invasive care through a comprehensive ecosystem of products and services.").

Intuitive Surgical Form 10-K For the Fiscal Year Ended December 31, 2001 ("Intuitive 2001 Form 10-K") at p. 4-5; Intuitive 2021 Form 10-K at p. 6-8.

Interchangeable instruments were a "re-design" for the second prototype (named "Mona," which was the first prototype that was tested in human surgery) prior to the commercialization of the da Vinci Surgical System. The interchangeable instruments was a "key feature missing in the Lenny prototype and essential for first human use. It meant not only that the system could accommodate many different styles of instruments for different surgical tasks, but also that these instruments could be separated from the non-sterile robotic manipulators and sterilized independently." *See* Intuitive-00270554 at -561-562.

C. FROM THE BEGINNING, INTUITIVE HAS BEEN SELLING THE DA VINCI SURGICAL SYSTEM AS AN INTEGRATED PRODUCT

65. Intuitive always has sold its product as a surgical system and always has been transparent about the lifetime costs of the system. Specifically, customers are informed from the outset that the system design includes both capital and "smart disposable" components and that their costs would include up-front capital costs associated with the da Vinci platform as well as periodic costs associated with the instruments. Below, I describe Intuitive's approach at the time of the first da Vinci Surgical System in 1998 through the present.

1. Intuitive designed the da Vinci Surgical System to be sold as an integrated product

66. Intuitive's historical Form 10-K filings show that Intuitive has sold an integrated system since at least 2001, and I am aware of no evidence that Intuitive ever separately sold the components of a da Vinci Surgical System. In its 2001 Form 10-K, Intuitive stated that its "da Vinci Surgical System consists of a surgeon's console, a patient-side cart, a high performance vision system and our proprietary instruments." Intuitive characterized the system as "an advanced surgical system that we believe represents a new generation of surgery – the third generation," where open surgery and minimally invasive surgery are the two prior generations. As of 2001, Intuitive had sold 89 systems and recorded net losses of \$16.7 million. Although the company had not yet had a year ending with positive net income, Iso Intuitive chose to offer an

¹⁷⁴ Intuitive 2001 Form 10-K at p. 4.

 $^{^{175}}$ See, e.g., Intuitive-00005135, \S 8 (on Instruments and Accessories) and \S 9.2 (on Pricing and Payment Terms of Services).

Intuitive 2001 Form 10-K at p. 3 (italics in original). See also Intuitive 2000 Form 10-K at p. 1.

¹⁷⁷ Intuitive 2001 Form 10-K at p. 3.

 $^{^{178}}$ Id

¹⁷⁹ Intuitive 2001 Form 10-K at p. 19.

¹⁸⁰ *Id*.

integrated system (i.e., the da Vinci Surgical System) that would serve as an alternative method of performing surgery.

- 67. Intuitive is transparent in the expected costs that are associated with its systems, including a predictable increase in costs for increased scope of application or increased surgical volumes. First, Intuitive clearly states that EndoWrist instruments are "smart disposables" that are "resterilizable and reusable for a defined number of procedures or hours of use." An EndoWrist instrument should not be "used for more than the prescribed number of procedures or hours so that its performance meets specifications during each procedure. In addition, [Intuitive] can sell the instrument for a fixed number of uses or hours and effectively price [its] EndoWrist instruments on a per-procedure or per-hour basis." ¹⁸²
- 68. Second, Intuitive has always made clear that, although the majority of its revenues in the early years came from the sales of the da Vinci Surgical System (consisting of "a surgeon's console, a patient-side cart, a high performance vision system and proprietary instruments"), the company expected that its share of revenues from EndoWrist instruments would increase over time. ¹⁸³

 This is because Intuitive would receive "recurring revenue through sales of the EndoWrist instruments and accessories and ongoing service" over the "useful life of each installed da Vinci Surgical System." ¹⁸⁴ Customers that entered into an agreement with Intuitive were informed that there would be costs associated with the da Vinci platform and instruments into the future, depending on their scope and level of use. ¹⁸⁵

¹⁸¹ Intuitive 2001 Form 10-K at p. 5.

¹⁸² *Id*.

¹⁸³ Intuitive 2001 Form 10-K at p. 16.

 $^{^{184}}$ Id

e.g., in a model shared with Phoenixville Hospital, in the "Reinvestment ROI" tab, the contribution margin for the hospital per procedure is estimated as a function of instrument, accessory, and operating room costs (Intuitive-00001639). *See also* "Discovery and Bus. Plan Inputs" and "FinancialProforma" tabs (Intuitive-00001639).

2. Intuitive continuously has been selling the da Vinci Surgical System as an integrated product while innovating on various components

- 69. Since 2001, Intuitive has developed four "generations" of da Vinci platforms and a wide variety of EndoWrist instruments. ¹⁸⁶ For example, among other innovations relative to its predecessors, the da Vinci Xi System (which is the fourth generation) allows healthcare providers to work "much deeper or much farther into the body," and all components—including the platform and instruments—needed to "evolve" with the new system. ¹⁸⁷ Evidence indicates that Intuitive's innovations provide surgeons with more control, precision, and choice over how to perform surgery. ¹⁸⁸
- 70. While Intuitive has innovated on the da Vinci Surgical System over the past two decades, the company continues to sell the system as an integrated product (including the platform and

See ¶ 29 above and McGrogan (in Rebotix) Dep. Tr. 15:7-20 ("Q. Have those model numbers evolved over the years? A. There are various models of da Vinci that have come out. IS1200 was the first one, then IS2000, then IS3000, then IS4000, then IS4200. That's at least a multiport robot sort of generation. Q. And you tell me which da Vinci robot each of those numbers corresponds to? A. Oh. I think the IS1200 is referred to as the standard. ...IS2000 is referred to as the da Vinci S. IS3000 is the da Vinci Si. IS4000 is the da Vinci Xi. And IS4200 is the da Vinci X."); Longmore et al. at p. 13 on da Vinci instruments ("Due to being commercially available for twenty years, the da Vinci RAS system has the largest library of end effectors available of all RAS systems (Table 5. Instruments). Not only does the da Vinci RAS system have the largest variety of end effector types, it also has a large variety of each type of end effector. For example, da Vinci has twelve different forceps available for the surgeon to choose from.").

McGrogan (in *Rebotix*) Dep. Tr. 79:9-21 ("A. The -- the platforms had different surgical goals. The Xi had expanded goals for surgery that the Si platform didn't have. And that drove, amongst other things, a lengthening of the instrument as a primary requirement, which made – and lengthening means working deeper in the body. So we wanted to enter at one port location and work much deeper or much farther into the body, and that drove for a longer instrument. And that, among other requirements, made us evolve the platform, the robot, and the instrument to go along with it.").

¹⁸⁸ See, e.g., "About the da Vinci Surgical System," UC Health, accessed January 6, 2023, https://www.uchealth.com/services/robotic-surgery/patient-information/davinci-surgical-system/ ("Robotic-assisted surgery with the da Vinci Surgical System allows surgeons to perform complex minimally invasive surgical procedures with precision and accuracy. The system is an advanced robotic platform designed to expand the surgeon's capabilities and offer an option to open surgery.").

instruments) as it had with its first system in 1998.¹⁸⁹ In its sales, licensing, and servicing agreement ("SLSA") with customers and public filings, Intuitive has been transparent about its policies regarding EndoWrist instruments:

a. By signing the SLSA, customers expressly acknowledge that the "System is designed for use only with the Instruments and Accessories"¹⁹⁰ and that "Intuitive does not have an obligation to provide Services (1) on any System where installation, repair, or adjustments have been made by an individual other than an Intuitive technician or an individual approved by Intuitive or (2) which are either necessary or desired as a direct or indirect result, in whole or in part, of unauthorized repair, modification, disassembly, alteration, addition to, subtraction from, reconfiguration, or misuse of the System."¹⁹¹ Customers also acknowledge that they "will not, nor will Customer permit any third party to, modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories."¹⁹² Such provisions concerning the use of the system and instruments have been included in the agreements since 1999. ¹⁹³

¹⁸⁹ See fn. 46 above.

LARKIN-00025488 ("Use, License & Service Agreement" between Intuitive and Larkin Community Hospital dated June 9, 2017), § 5.2(E) ("The System is designed for use only with the Instruments and Accessories. If Customer uses the System with any surgical instrument or accessory not made or approved by Intuitive, Intuitive may discontinue Services, and any warranties applicable to any Services provided prior to any discontinuance will be void."). The agreement defines "Instruments and Accessories" as "instruments or accessories made or approved by Intuitive for use with the System." LARKIN-00025488, § 2.3. See also VMC-00020652 ("Sales, License, and Service Agreement" between Intuitive and Valley Medical Center signed on August 31, 2018), § 5.2(E).

LARKIN-00025488, § 5.2(A) ("Intuitive does not have an obligation to provides Services (1) on any System where installation, repair, or adjustments have been made by an individual other than an Intuitive technician or an individual approved by Intuitive or (2) which are either necessary or desired as a direct or indirect result, in whole or in part, of unauthorized repair, modification, disassembly, alteration, addition to, subtraction from, reconfiguration, or misuse of the System, or negligence or recklessness on the part of Customer."). See also VMC-00020652, § 5.2(A).

¹⁹² LARKIN-00025488, § 3.4 ("Customer will not, nor will Customer permit any third party to, modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories.") and VMC-00020652, § 3.4.

See, e.g., Intuitive-01524447 ("Master Purchase and Master Service Agreement" between Intuitive and Beth Israel Medical Center dated October 15, 1999), §§ 3.2(c)-(d) and 2.4(b);

- b. In its Form 10-Ks, Intuitive states that it offers a variety of instruments "customized for various surgical procedures." ¹⁹⁴ In addition, instruments have a "programmed memory chip" that informs "how the da Vinci system and instruments work together. In addition, the chip will generally not allow the instrument to be used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure." ¹⁹⁵ This language has remained consistent since 2001. ¹⁹⁶
- c. Intuitive's Form 10-K also describes its business model. In 2001, the company disclosed that "[d]uring the useful life of each installed *da Vinci* Surgical System, we expect to generate recurring revenue through sales of the EndoWrist instruments and accessories and ongoing service." ¹⁹⁷
- 71. Evidence indicates Intuitive has always been transparent regarding its pricing for EndoWrist instruments, including during its initial system contracting. ¹⁹⁸ Nonetheless, it is evident in

and Intuitive-01291299 ("Sales Agreement" between Intuitive and Pitt County Memorial Hospital dated October 20, 1999), §§ 3.2(c)-(d) and 2.4(b).

¹⁹⁴ Intuitive 2020 Form 10-K at p. 7.

¹⁹⁵ Id

Intuitive 2001 Form 10-K at p. 5 ("A custom computer chip inside each instrument performs several functions that help determine how the system and instruments work together. ...In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures or hours so that its performance meets specifications during each procedure."); Intuitive 2021 Form 10-K at p. 8 ("A programmed memory chip inside each instrument performs several functions that help determine how the da Vinci system and instruments work together. In addition, the chip will generally not allow the instrument to be used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure.").

¹⁹⁷ Intuitive 2001 Form 10-K at p. 16.

See, e.g., Intuitive-00279920, Intuitive-00279923 ("Da Vinci Si, Instrument & Accessory Catalog With Pricing in US Dollars," February 2018), and Intuitive-00279958 ("Da Vinci X and Da Vinci Xi, Instrument & Accessory Catalog with pricing in US dollars," January 2018). Intuitive analyzed OU Medicine's average instruments and accessories ("I&A") cost per procedure and noted that "[t]here is no fundamental difference in cost between Si and Xi on like items" (Intuitive-00279920 at -921). Intuitive also enclosed its "current online instrument catalogs which should provide more clarity" (Intuitive-00279920 at -920).

Intuitive's sales data that the particular instruments purchased by customers depend on the levels and nature of the specific surgeries being performed.

72. As shown above, Intuitive marketed the da Vinci Surgical System as an integrated product with various instruments that may be used depending on surgery type and then (once any applicable usage limit is met) need to be safely replaced by Intuitive. Nonetheless, Dr. Lamb claims that Intuitive views the da Vinci platforms (i.e., "MIST Surgical Robots") and EndoWrist instruments as separate products, citing product descriptions in Intuitive's 2021 Form 10-K. ¹⁹⁹ However, Dr. Lamb overlooks that Intuitive's use of the term "da Vinci Surgical System" includes the platform as well as its "proprietary instruments and accessories." ²⁰⁰ Moreover, Intuitive's public descriptions of the da Vinci Surgical System are consistent with the creation and sale of an integrated surgical system as a whole. ²⁰¹

D. OTHER MANUFACTURERS OF ROBOTIC-ASSISTED SURGICAL SYSTEMS ALSO SELL THEIR SYSTEMS AS INTEGRATED PRODUCTS

73. Intuitive's decision to sell the da Vinci Surgical System as an integrated product is not unique in the medical device industry. In particular, there are other manufacturers of RAS systems facing the same component complementarities and negative externalities, which also choose to sell their

As discussed in Section V.B below, Intuitive's I&A sales data confirms that the majority of customers pay the same price for a specific instrument and that instrument prices have not been increasing over time.

¹⁹⁹ Lamb Report ¶ 74.

Intuitive 2021 Form 10-K at p. 88 ("Intuitive Surgical, Inc. ('Intuitive' or the 'Company') develops, manufactures, and markets the da Vinci Surgical System and the Ion endoluminal system. The Company's products and related services enable physicians and healthcare providers to improve the quality of and access to minimally invasive care. The systems consist of a surgeon console or consoles, a patient-side cart, a high-performance vision system, and proprietary instruments and accessories.") (emphasis added).

²⁰¹ See, e.g., Intuitive 2021 10-K at p. 88 ("The systems consist of a surgeon console or consoles, a patient-side cart, a high-performance vision system, and proprietary instruments and accessories.").

surgical systems as integrated products, including systems that so far have significantly fewer sales than Intuitive—e.g., CMR Surgical.

- 74. Similar to Intuitive, CMR Surgical sells a "closed system" (i.e., systems that have specifically designed instruments and are not compatible with other instruments) with usage limits on instruments. CMR Surgical manufactures the Versius Surgical Robotic System ("Versius System") for minimally invasive surgeries. ²⁰² The company was founded in 2014 and currently has regulatory approval in the UK, EU, India, and Australia. ²⁰³ As of June 2020, CMR had sold nine systems in the UK and India. ²⁰⁴ The Versius System only uses "surgical instruments and consumables specifically designed for the Versius System… as the Versius System is a closed system," ²⁰⁵ and instruments have a maximum usage of 13 procedures. ²⁰⁶ Although CMR Surgical has far fewer installations than Intuitive to date, the company decided to sell an integrated system with instruments that were specifically designed for it and that had usage limits.
- 75. It is worth noting that there are also differences in the business models employed by manufacturers of RAS systems and that these differences are a dimension along which the systems can compete. Whereas Intuitive and CMR Surgical generally have "closed" systems with specifically designed instruments, Medrobotics and TransEnterix²⁰⁷ (manufacturer of the Senhance Surgical System) promote their "open architecture" that allows third-party instruments

²⁰² CMR-00001108, ¶ 2.

 $^{^{203}}$ CMR-00001108, ¶ 4.

²⁰⁴ CMR-00001108, ¶ 5.

 $^{^{205}}$ CMR-00001108, ¶ 3.

 $^{^{206}}$ CMR-00001108, ¶ 9.

TransEnterix changed its name to Asensus Surgical as of March 5, 2021. See "TransEnterix Announces Name Change to Asensus Surgical and Introduces a New Category of Surgery, Performance-Guided Surgery," Business Wire, February 23, 2021, accessed January 6, 2023, https://www.businesswire.com/news/home/20210223005444/en/TransEnterix-Announces-Name-Change-to-Asensus-Surgical-and-Introduces-a-New-Category-of-Surgery-Performance-Guided-Surgery. Because the company is referred to as "TransEnterix" in the documents in this case, I will refer to it as "TransEnterix" in my report.

to be used with their systems. ²⁰⁸ However, it is unclear how open the Medrobotics system actually will be in practice, as, at least with one customer, Medrobotics holds the option to terminate an agreement "if UMMC uses the system with any accessory not made *or approved by* Medrobotics" or if "UMMC tampers with or alters the system, software of any accessories" and does not address the issue within 30 days of written notification from Medrobotics. ²⁰⁹ Another differentiating factor of the Senhance System that TransEnterix highlights is that instruments for the system have "no hard limit to the number of times an instrument may be reused." ²¹⁰ These examples show that manufacturers choose business models that work best for their products and competitive position and that differences in these arrangements are a way in which they compete.

76. As a matter of economics, the similarities in system-product designs—like Intuitive's and CMR Surgical's—confirm that some robotic platforms, instruments, and service are so interdependent in terms of product design, quality, and performance that they should be considered as one product as a whole.

IV. PLAINTIFF'S ASSERTED "TYING" MARKET SHOULD INCLUDE LAPAROSCOPIC AND OTHER SURGICAL SOLUTIONS

77. Even if one accepts, for purposes of argument, that Intuitive's da Vinci platforms and EndoWrist instruments are distinct "products," Dr. Lamb offers no compelling economic analysis that the alleged "tying" product is a "monopoly." Dr. Lamb tautologically asserts that Intuitive monopolizes its own product which effectively constitutes a relevant antitrust market because it is different from, and in many ways superior to, other products. On the contrary, applying

[&]quot;Flexible 'open architecture' instrumentation," Medrobotics, accessed January 6, 2023, https://www.easmed.com/surgical-robot-flex-system/; "The Senhance Surgical System is the first and only digital laparoscopic platform," Senhance, accessed January 6, 2023, https://www.senhance.com/us/digital-laparoscopy. *See also* Asensus Surgical Form 10-K For the Fiscal Year Ended December 31, 2020 at p. 9 ("We also have designed the Senhance System so that third- party manufactured instruments can be easily adapted for use."). *See also*

Mississippi Board of Trustees at p. 37 (emphasis added). UMMC is The University of Mississippi Medical Center. See, Mississippi Board of Trustees at p. 36.

Longmore et al. at p. 15. Senhance is the only system among the six systems listed in Table 5 (including da Vinci Xi and da Vinci Single Site) that has "infinite" instrument reusability.

economic principles to the evidence in this case confirms that Intuitive's surgical systems compete in a broader market for surgical solutions, and have since the da Vinci Surgical System's inception.

A. DR. LAMB'S ASSERTED "TYING" MARKET AND PROFFERED SUPPORT

- 78. Dr. Lamb asserts that his so-called "tying" market (which he calls the "market for MIST Surgical Robots") and his "tied" market (which he calls "the EndoWrist Repair and Replacement Market") constitute separate relevant antitrust product markets, and points to evidence that purports to show that the "hospital demand for the two products is distinct." This assertion is relevant, according to Dr. Lamb, because "[i]n the context of a tying arrangement, courts have held that products are considered distinct if there is sufficient demand for the tied product separate from the tying product." 212
- 79. Dr. Lamb also purports to conduct a so-called SSNIP test separately for his two proposed antitrust markets (the tying and the tied) in support of his conclusion that they are separate. In antitrust analysis, a SSNIP test is a commonly used framework for identifying and delineating the boundaries of antitrust markets. However, as addressed below, Dr. Lamb's implementation of the SSNIP test to identify relevant markets ignores the central goal of market definition—to illuminate competitive effects. Under this standard, the product "markets" defined by Dr. Lamb are not *relevant* antitrust markets.

²¹¹ Lamb Report, ¶¶ 70, 73.

²¹² Lamb Report, ¶ 71.

The SSNIP test is also referred to as the "Hypothetical Monopolist Test." *See* U.S. Department of Justice and the Federal Trade Commission 2010 Horizontal Merger Guidelines ("HMG"), § 4.1.

²¹⁴ HMG, § 4.

- B. THE PROPER ANALYTICAL FRAMEWORK FOR ASSESSING INTUITIVE'S ALLEGED MONOPOLY POWER IN THE "TYING" MARKET
- 80. In considering Dr. Lamb's proposed "tying" market and alleged monopoly power of the da Vinci platform, it is important first to understand the proper economic framework and principles that should inform such an inquiry. This is particularly important here, where those making purchasing decisions (healthcare providers, surgeons, and patients) are choosing among significantly differentiated surgical solutions, and doing so on a life-cycle cost basis.
- 81. Ultimately, the economic question of Intuitive's asserted monopoly power is whether these customers, in considering Intuitive's surgical solution, have competitive options that effectively constrain Intuitive's competitive behavior—i.e., to ensure that Intuitive must compete to win and keep business. This assessment centers on the time and context of contracting, and in particular consideration of those products that are Intuitive's closest competitors, and whether those options for the customer have a constraining effect on Intuitive's competitive behavior. The assessment must also consider whether there are constraining effects that continue over each year of a customer's lifetime as a da Vinci Surgical System customer as well.
- 82. In assessing the allegations in this case of an extension of monopoly power in one relevant market to achieve monopoly power in another, we have the benefit of being able to look at what historically has influenced Intuitive's competitive decision-making, and whether Intuitive's competitive behavior meaningfully has changed in a way that reflects increased monopoly power as its sales of surgical systems have grown. This analysis involves an evaluation of the competitive constraints Intuitive faced when it first developed and marketed the da Vinci Surgical System, as well as how those competitive constraints have evolved over time. For example, two key considerations here are (i) whether, as it succeeded, Intuitive raised prices to extract surpluses that reflect monopoly power (i.e., well beyond those necessary for Intuitive's expected revenues to exceed its investment and operational costs); and (ii) whether Intuitive "price discriminated" where its product was most in demand and thus arguably it had the most market power. If neither of these features of anticompetitive conduct is evident, it is a strong indication that Intuitive remained competitively constrained, even as it achieved commercial success—winning competitions is evidence of competition, not the lack thereof.

83. As I describe below, evidence supports a surgical solutions marketplace in which Intuitive's surgical system is one among other competitive options for hospitals and where Intuitive is particularly focused on competition with its closest substitutes—laparoscopic and open surgeries. The only rational economic conclusion is that both at its origin, and now, Intuitive's surgical solution is not effectively its own "market;" nor is there evidence that it has any more power to impose an anticompetitive tying arrangement today than it did when it first came to market. Instead, evidence shows that Intuitive continually has innovated and competed to win and retain business, and has not acted as a monopolist of surgical solutions.

C. SURGICAL SOLUTIONS ARE DIFFERENTIATED PRODUCTS

84. Surgical solutions, including the da Vinci Surgical System, are what economists refer to as differentiated products. These are products that are substitutable for one another, and may be highly substitutable for one another, but they are not *perfect substitutes*. The demand for a particular differentiated product depends on the specific characteristics the product offers as well as consumers' specific preferences, tastes, and needs for these characteristics. There are several characteristics that differentiate the da Vinci Surgical System from other surgical solutions, and make it a particularly attractive substitute for many other options, including: (i) its record of patient safety; (ii) its prevalence in academic and clinical research; (iii) the precision of the system including its EndoWrist instruments; (iv) the degree of precision and dexterity offered to surgeons while operating the system; (v) the number of surgical procedures that have been approved for use with the system; (vi) the available surgeon training and simulation programs available for surgeons; and (vii) Intuitive's 24-hour surgeon support hotline.

217

²¹⁵ Pindyck and Rubinfeld at p. 452 (emphasis added).

²¹⁶ See, e.g., Pindyck and Rubinfeld at pp. 455-56.

See "About the da Vinci Surgical System," UC Health, accessed January 6, 2023, https://www.uchealth.com/services/robotic-surgery/patient-information/davinci-surgical-system/ ("The da Vinci System has been successfully used in tens of thousands of procedures. Its safety and efficacy are documented in clinical publications and the literature supporting its use is extensive."). The da Vinci Surgical System has appeared in over 22,000 peer-reviewed publications in various clinical journals since 1998. See "Clinical Evidence,"

- System's "features and benefits to surgeons" covering several of the characteristics listed above. ²¹⁸ Dr. Lamb also emphasizes that the da Vinci Surgical System's characteristics are highly valued by hospitals, surgeons, and patients. As an example, Dr. Lamb discusses a 2014 article quoting a Minnesota hospital administrator who states "Patients want robotic surgery because it means shorter hospital stays and faster recoveries for them." ²¹⁹ Dr. Lamb also discusses what he calls the "non-clinical" benefits to hospitals, such as being able to market the da Vinci Surgical System to potential patients, ²²⁰ as well as the ability to attract and retain surgeons. ²²¹ These and other aspects of the da Vinci Surgical System differentiate it from other products and make it an attractive solution to hospitals, surgeons, and patients.
- 86. Dr. Lamb relies on the da Vinci Surgical System's differentiating features, which were developed under competition with other surgical options, to conclude that there are no substitutes close enough to the da Vinci Surgical System sufficient to keep Intuitive from imposing

Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/about-us/company/clinical-evidence. Intuitive offers a comprehensive suite of stapling, energy, and core instrumentation for the surgical systems. "Inspired by the human hand, our wristed instruments enable surgeons to orient the instruments carefully relative to the tissue and suture with precision, just as they can in open surgery." *See* Intuitive 2021 Form 10-K at pp. 6-7. The da Vinci Surgical System offers many benefits and features like immersive 3DHD visualization, precise and tremor-free endoscope control, and scaled, tremor filtered instrument movement to offer a high degree of precision and dexterity. *See* Intuitive 2021 Form 10-K at pp. 6. Da Vinci Surgical Systems are cleared to perform cardiothoracic surgery, general surgery, gynecologic surgery, head and neck surgery, and urologic surgery. *See* Intuitive 2021 Form 10-K at pp. 8-9. Intuitive offers online learning, simulation and hands-on training for da Vinci technology. *See* Intuitive 2021 Form 10-K at pp. 9. Intuitive offers 24x7 worldwide technical system support for da Vinci Surgical Systems. *See* "Contact," Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/about-us/contact.

²¹⁸ Lamb Report, \P 38.

²¹⁹ Lamb Report, ¶ 40, quoting from a February 2014 article from *The Rural Monitor*.

For instance, Dr. Lamb quotes from a 2004 academic article stating "It is not uncommon, for example, to see a photo of a surgical robot on the cover of a hospital's marketing brochure and yet see no word mentioning robotic surgery inside." Lamb Report, ¶ 40, quoting from an Annals of Surgery article.

²²¹ Lamb Report, ¶¶ 42-44.

monopoly pricing and anticompetitive contractual provisions. Similarly, in concluding that "the market for MIST Surgical Robots constitutes a relevant antitrust product market," he states that "...traditional laparoscopic surgeries are, at best, only limited functional substitutes and not economic substitutes for minimally invasive soft tissue surgeries performed using MIST Surgical Robots." 223

87. What matters for assessing these assertions from an economic perspective is whether the demand for the da Vinci significantly is affected and constrained by the potential for substitution to other surgical solutions. Indeed, Dr. Lamb appears to acknowledge the need for such an inquiry as he begins his description of the relevant antitrust market. He states:

"In general, an economic analysis of the relevant antitrust product market requires identifying 'products that are close demand or supply substitutes.' That is, a relevant market should contain all the products which are substitutable for each other in the face of small but significant, non-transitory price increases; an analysis of the relevant market thus necessarily focuses on an analysis of *economic* substitutability."²²⁴

88. It is well-recognized in economics that, as a differentiated product, the da Vinci Surgical System can face vigorous competition from other, differentiated, surgical solutions, including laparoscopic and open surgeries. I show below that the relevant product market for assessing

Specifically, Dr. Lamb states: "I base this conclusion on the fact that there are no economic substitutes for minimally invasive soft tissue surgeries performed with MIST Surgical Robots and that MIST Surgical Robots are a necessary input in performance of those surgeries." Lamb Report, ¶ 27. He further states: "[O]ther forms of minimally invasive soft tissue surgery (such as traditional laparoscopic surgery) and non-MIST robotic surgeries are not economic substitutes for robotically assisted minimally invasive soft tissue surgeries. Therefore, because there are no economic substitutes for robotically assisted minimally invasive soft tissue surgeries, which are defined by the use of the MIST Surgical Robot (of which da Vinci is the dominant type during the Relevant Period), there are no economic substitutes for MIST Surgical Robots." Lamb Report, ¶ 27.

Lamb Report, ¶ 30. Dr. Lamb's assertion is incomplete. Any surgery that can be performed using a da Vinci Surgical System can be achieved through alternative surgical modalities.

Lamb Report, ¶ 27 (emphasis in original). Dr. Lamb's incorporation of the concept of "supply substitutes" is inapt, because, as the HMG state: "Market definition focuses solely on demand substitution factors. . . ." (HMG, § 4).

Intuitive's competitive focus, including the conduct at issue in this matter, necessarily includes those other surgical modalities and systems. As I discuss below, contrary to Dr. Lamb's opinion, the demand for the da Vinci Surgical System is "derived" from the demand for surgeries, and the closest competition to the da Vinci since its inception for those surgeries has come from surgeries performed laparoscopically, where the da Vinci has always competed vigorously and must continuously do so to win over and maintain demand from hospitals, doctors, and patients.

- D. THE DEMAND FOR DA VINCI SURGICAL SYSTEMS IS DERIVED FROM THE DEMAND FOR SURGERIES AND OPTIONS AVAILABLE TO HOSPITALS AND THEIR DOCTORS
- 89. Surgeries that can be performed either with the da Vinci Surgical System or with other surgical solutions and modalities (i.e., laparoscopic and open surgery), are at the core of a given hospital's demand for the da Vinci Surgical System. But Dr. Lamb's tautological characterization of this relationship is flawed as he myopically focuses on the demand for robotic surgeries while evidently dismissing the economic substitutability of other surgical solutions. Hence, Dr. Lamb describes the market for surgeries as a so-called "output" market whereas the market for MIST Surgical Robots is an "input" market. 225
- 90. This is incorrect as a matter of economics. The purported basis for Dr. Lamb's conclusion that MIST Surgical Robots is a "relevant antitrust product market" is that "there are no economic substitutes for minimally invasive soft tissue surgeries performed with MIST Surgical Robots and that MIST Surgical Robots are a necessary input in performance of those surgeries." The delineation between his output market (of surgeries performed with the da Vinci Surgical System) and input markets (of the da Vinci platform and EndoWrist instruments) overlooks the economic reality that demand for the "inputs" is primarily driven by (i.e., "derived" from) demand for surgeries performed with MIST Surgical Robots.

Lamb Report, ¶ 28. Presumably, under Dr. Lamb's framework, his tied market (his so-called market for EndoWrist Repair and Replacement) would also constitute an input market as well.

²²⁶ Lamb Report, ¶ 27.

- 91. In economics, the term "derived demand" refers to demand "for an input that depends on, and is derived from, both the firm's level of output and the cost of inputs." This concept is relevant to understanding the demand for the da Vinci Surgical System, which has its demand derived from the demand for surgeries.
- 92. Evidence indicates that surgeon demand is often, if not usually, the initiating factor that causes hospitals to rent or acquire a da Vinci System. Mr. Early at Larkin Community Hospital noted that the hospital would not have acquired a da Vinci System unless they expected surgeons to use it.²²⁸ At other hospitals, surgeons themselves repeatedly requested a da Vinci System until their requests were noted in formal and informal equipment acquisition processes and fulfilled.²²⁹ The promise of a da Vinci System was also used in the hiring process to attract surgeons to certain hospitals over others. ²³⁰Testimony of Tyler McDonald, director of surgical services at Conway

²²⁷ Pindyck and Rubinfeld at p. 530.

Early (10/6/2022) Dep. Tr. 193:25-194:10 ("Q. Thinking back before the, Larkin purchased the Da Vinci Surgical Systems, did you tell Ms. Sosa-Guerrero that Larkin should not purchase those -- the robots? A. No, not that I can recall. Again, I, if the physicians were -- if the physicians were not going to use it, of course that would have been no. But the physicians were going to come. And I don't think anybody would have planned on acquiring that equipment if the expectation wasn't that physicians would use -- utilize that equipment.").

Schimmel (9/22/2022) Dep. Tr. 25:23-26:16 ("Q. When did the Lafayette location of Franciscan start using da Vinci surgical systems for surgeries? A. 2009. Q. And why did Franciscan Lafayette first start using the da Vinci machines? ... [A.] We had GYN physicians make the request. Q. And why did they say they wanted the da Vinci surgical robots available for their use? ... [A.] I don't remember. Q. Do you remember the names of the GYN surgeons who made that request? A. I do. Dr. McKweg, Dr. Wickert, Dr. Harrison were top three.").

Wagner (10/11/2022) Dep. Tr. 44:15-25 ("Q. And what was the nature of that discussion? A. The nature of that discussion primarily was with surgeons, they were under the -- under -- we had an understanding that the Si robot was nearing end of life, reported to us that it was one of the oldest in the state, in fact, I seem to recall that they had shared with us -- they, meaning da Vinci, that it was one of the oldest on the West Coast, and there was a need and a desire from surgeons to want to use the Xi robot, and so we had ongoing discussions…").

Estape (10/22/2022) Dep. Tr. 22:12-21 ("Q. ...At some point, am I right, you had a relationship with Larkin Community Hospital? A. Yes. When I left Baptist Health, Larkin Hospital was almost literally across the street from one of the Baptist Health hospital at South Miami, and that's right were my office was at. And so I spoke with the director there

Regional Medical Center,²³¹ reflects the relationship between demand for the da Vinci robot and demand for a surgical procedure. In considering whether or not to upgrade from a da Vinci Si to a da Vinci Xi, McDonald acknowledged that the decision was influenced by the number of procedures they expected to perform with it.²³² He goes on to acknowledge that they compare the costs and benefits of robotic surgery with other surgical modalities.²³³

93. Dr. Lamb appears to acknowledge that demand for the da Vinci Surgical System is derived from the demand for surgeries elsewhere in his report. From his "review" of "[a]dditional" documents, Dr. Lamb asserts that "MIST Surgical Robots and EndoWrist surgical instruments are separate, distinct products that are *inputs into the same product*"²³⁴—an acknowledgement that economic competition flows from competition at the surgical solutions level, ²³⁵ where, as I describe in the next section, Intuitive competes, and always has, against other surgical options that are Intuitive's closest substitutes.

and they were very willing to have me come over and buy two robots for me and for me to be able to do the cases there at Larkin Hospital.").

²³¹ McDonald (in *Restore*) Dep. Tr. 9:3-5 ("Q. What is your position at Conway Regional? A. My position is the director of surgical services.").

McDonald (in *Restore*) Dep. Tr. 51:21-52:4 ("Q. What would be the types of factors that you would include in your forecast evaluating the benefits of using a da Vinci Xi? A. We would include the number of total cases that we would expect to use the robot, the types of cases that would be used, and the specific types of instruments that would be required for use, their costs, and the corresponding costs of the previous generation's model.").

McDonald (in *Restore*) Dep. Tr. 52:16-25 ("Q. Other than the literature, have you done any internal analysis of costs that Conway has incurred itself when looking at benefits from robotic-assisted surgery? A. Yes. Q. And what have you done? A. We've reviewed our total costs, our length of stay expectations and history for these patients versus patients done with similar procedures absent the robot. That's primarily the mode of operation there.").

Lamb Report, ¶ 70 (emphasis added). Dr. Lamb does not explicitly state what he means by "inputs into the same product," although in ¶ 28, Dr. Lamb refers to "the market for or [sic] minimally invasive soft tissue surgeries performed with MIST Surgical Robots" as the "output market."

Despite this apparent acknowledgement by Dr. Lamb, I disagree with his characterization here that "MIST Surgical Robots and EndoWrist surgical instruments are separate, distinct products..." *See* Lamb Report, ¶ 70.

E. RELEVANT PRODUCT MARKETS SHOULD INCLUDE A PRODUCT'S CLOSEST COMPETITORS

- 94. Relative substitutability among products should drive the market definition analysis for Intuitive's surgical solutions. One standard way to construct a relevant antitrust market is to consider a product's substitutes in order of closeness. ²³⁶ Under this method, a proper starting point is to consider what are a hospital's or surgical center's other options, starting with the closest substitutes, when considering whether to purchase the da Vinci Surgical System.
- 95. Since the introduction of the da Vinci Surgical System, Intuitive has been focused on its ability to compete for market access with other surgical modalities, especially open surgery and laparoscopy. This effort starts with convincing a given hospital or surgical center that choosing to invest in the da Vinci Surgical System would be beneficial, given the alternative solutions, for the approved uses of the da Vinci Surgical System. It is not surprising that comparisons to alternative forms of surgery, primarily laparoscopy and open, are a central focus of Intuitive's marketing efforts with customers about their prospective purchase of the da Vinci Surgical System. I will highlight here two dimensions that are evident from these efforts.
- 96. First, Intuitive compares the clinical efficacy of the da Vinci Surgical System against outcomes from laparoscopy and open surgery.²³⁹ It does this by drawing from a large body of academic studies that make these comparisons using control groups of either laparoscopic surgery, open

In the economics of antitrust, this is the so-called "circle principle." That is, in building a relevant market around product A, if product C is included in a candidate market, and product B is a closer substitute for product A than product C, then product B also should be included in the relevant market. *See* HMG, § 4.1.1.

Intuitive 2000 Form 10-K at p. 2 ("Our products are designed to make a broad range of open surgical and MIS procedures suitable for Intuitive surgery. The da Vinci Surgical System is designed to allow surgeons to perform better surgery while providing patients with the benefits of MIS surgery. We believe that these advantages will enable us to drive a fundamental change in surgery.").

Intuitive 2000 Form 10-K at pp. 4-5. Intuitive advertises its advantages over alternative surgical solutions like open and laparoscopic surgery to hospitals and patients alike. *See also* Intuitive-00000339 for an example of Sales Reference Materials for hospitals.

²³⁹ Intuitive-00065233.

surgery, or both.²⁴⁰ According to these studies, example benefits of the da Vinci Surgical System are a reduced frequency of surgical site infections and a shorter post-surgery hospital stay on average, when compared to laparoscopy and open surgery.²⁴¹ It is worth noting that, while several studies highlight the favorable clinical outcomes resulting from use of the da Vinci Surgical System, there are competing studies concluding that the efficacy of the da Vinci is not significantly better than that of laparoscopic and open solutions.²⁴²

97. Second, Intuitive compares the costs of the da Vinci Surgical System against those of using laparoscopy and open surgery, including after taking into consideration the savings resulting from the da Vinci's clinical benefits. A customer's decision to invest in a da Vinci Surgical System should consider its expected costs of operating the system over the system's lifetime when compared to alternatives. Given the size of the customer's investment, Intuitive has pointed out to prospective customers that any expected cost savings attributable to da Vinci's benefits should be factored in as well when making such comparisons. Intuitive has explained that if a patient undergoes a da Vinci procedure and requires one less day spent recovering in the hospital relative to the expected stay from undergoing the same procedure through use of another modality, the hospital's financial cost savings from that one less day of recovery time can be an

²⁴⁰ See, e.g., Dhanani et al. at pp. 1-2.

²⁴¹ See, e.g., Dhanani et al., Appendix Table 6.

Dhanani et al. state (at p. 3): "We found slight decreases in both intraoperative and Clavien—Dindo complications with robot-assisted surgery, with increases in operative duration and cost; however, most studies failed to show significant benefit compared with current practices."

For example, as discussed above, customers are made aware of the integrated aspect of the da Vinci Surgical System and the associated costs with operating it. *See* Section III.C above.

important factor when choosing which mode to use.²⁴⁴ I understand that Intuitive refers to these marketing efforts as "Quantify the Impact" (QTI).²⁴⁵

- 98. Dr. Lamb's claim that "traditional laparoscopic surgeries are, at best, only limited functional substitutes....for minimally invasive soft tissue surgeries performed using MIST Surgical Robots" is contradicted by surgeon testimony, ²⁴⁶ which reflects that da Vinci, laparoscopic, and open surgical techniques are often used interchangeably for the same procedure. For example:
 - Dr. Ricardo Estape, a gynecologic oncology surgeon at Larkin Community Hospital
 ("Larkin") and director for HCA Florida's Institute for Gynecologic Oncology, stated that he
 makes the choice between open, laparoscopic, and robotic surgical modalities every day.²⁴⁷
 - Similarly, Dr. Greta Bernier, chief of surgery for the medical staff office at Valley Medical Center, acknowledged that there are no procedures for which she exclusively uses a single modality.²⁴⁸

Intuitive-00001237 at -263 ("From a cost standpoint instruments and accessories are just the 'tip of the iceberg' as it relates to total cost to treat... This is an incomplete view unless you quantify the potential cost offsets associated with clinical measures such as LOS [Length of Stay], ICU admission, conversions [to costlier open surgeries], complications, surgical site infections, PACU [Post-Anesthesia Care Unit] time, readmission, and blood transfusions."). *See also* Intuitive-00001788 at -816, -818, -820, and -849.

Of course, through one less day in the hospital, the patient's experience is likely to be enhanced as well.

²⁴⁵ Intuitive-00001788 provides an overview of the QTI process. Intuitive-00038260 is a specific example of a QTI presentation to Essentia St. Joseph's Hospital, incorporating the hospital's own data.

²⁴⁶ Lamb Report, ¶ 30.

²⁴⁷ Estape (10/22/2022) Dep. Tr. 7:24-8:1; Estape (10/22/2022) Dep. Tr. 19:7-10 ("Q. Are there times when you have an option to choose between open vaginal, lap or robotic surgery modalities? A. Every day.").

Bernier (11/7/2022) Dep. Tr. 19:2-4 ("Q. Are there any surgeries that you perform exclusively using one modality and not the others? A. No."). *See also* Bernier (11/7/2022) Dep. Tr. 9:19-21 ("Q. What is your role at Valley? A. I am a colorectal surgeon at Valley, and I am the chief of surgery for the medical staff office.").

- Dr. Dipen Maun, a colorectal surgeon at Franciscan Alliance ("Franciscan"), also stated that he alternates between surgical modalities for the same procedure.²⁴⁹
- 99. Further, evidence from surgeons and hospital administrators indicates that cost is an important factor in the decision of surgical modality. For example, Larkin CEO Sandy Sosa-Guerrero stated that Larkin compared the price of performing procedures laparoscopically and robotically, and encouraged physicians to discuss the comparative costs with patients. ²⁵⁰ Moreover, Dr. Estape stated that Larkin hospital administrators have asked him to switch to laparoscopic procedures for Medicaid or Medicare patients rather than using the da Vinci robot due to

Maun (11/8/2022) Dep. Tr. 16:5-8 ("Q. Do you perform open endoscopic and robotic-assisted surgeries in addition to laparoscopic surgeries? A. I do."); Maun (11/8/2022) Dep. Tr. 17:25-18:8 ("Q. Which of those three procedures do you perform using the Da Vinci system? A. The rectal cancer operations. Q. Do you also perform rectal cancer operations laparoscopically? A. I do. Q. Do you also perform rectal cancer operations using the open modality? A. I do."). *See also* Maun (11/8/2022) Dep. Tr. 12:9-11 ("Q. Would you describe for me, please, your medical training. A. I am a board certified colorectal surgeon."); Maun (11/8/2022) Dep. Tr. 12:19-22 ("Q. After completing your fellowship, where did you practice medicine? A. This has been my one and only job here at Franciscan.").

²⁵⁰ Sosa-Guerrero (9/23/2022) Dep. Tr. 182:8-183:8 ("Q. Well, let me ask you this: Did you come to a point of view while you were the CEO of -- at Larkin that there were some procedures that Larkin should do laparoscopically and there were other procedures that they should do robotically from a financial standpoint? ... [A.] I don't make those decisions that -whether -- but when they would be coming to book them, we would say -- we would show the physician, this is what the insurance is going to cost, and the person, for -- for the most part, they had a high deductible in those cases, if they were robotics. High deductible. So I would say just tell the patient they have a \$5,000 deductible and see where they go. And then, for the most part, they will go back to a doctor and ask questions, you know, what's the difference? And they would end up choosing, between the physician and the -- the patient, what they wanted to do....Q. In terms of whether it was going to be a robotic procedure or laparoscopic? A. (Witness nodding.) Q. You have to say 'yes.' A. Yes."). See also Sosa-Guerrero (9/23/2022) Dep. Tr. 180:24-181:8 ("Q. Okay. In the discussion that you had with Mr. Gonzalez around the cost of robotic procedures, do you recall comparing the cost of robotic procedures to the cost of laparoscopic procedures? A. Yes. What I told him was I cannot make an assessment based on one case, you know. He needed to go back and do a spreadsheet with more cases, more insurance companies, providers, and then give me that, because this was just not going to sway me one way or the other.").

costs.²⁵¹ Dr. Burke, former chairman of the department of surgery at Valley Medical Center, ²⁵² similarly recognized that the cost of the procedure influenced the choice of surgical modality and pointed to gall bladder surgery as one procedure that was generally performed laparoscopically due to the costs of the da Vinci instruments for the procedure.²⁵³

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²⁵¹ Estape (10/22/2022) Dep. Tr. 21:1-16 ("Q. Have any of the hospitals that you've been associated with asked you not to perform a surgery in a particular way because of cost? A. Yes, sir. Q. What hospital or hospitals are you thinking of? A. Larkin is the only one. Q. And what did Larkin ask of you on that topic? A. Larkin at one point in time didn't want me to do any of the Medicaid patients or Medicare patients through the -- and this was right near the end when it came time for me to leave there. They were asking me not to do those cases because they didn't think they were making money on those patients."). See also Sosa-Guerrero (9/23/2022) Dep. Tr. 42:3-43:2 ("A. Because most of the patients that Dr. Estape had had both Medicare and Medicaid. When he first came, he told us he had more private insurance. We -- which pays at a higher rate. When he started doing the actual surgeries, the -- the patients that were coming through were mostly Medicare and Medicaid. Medicare nor Medicaid pay for robotic surgery. Q. Did Medicare and Medicaid pay for laparoscopic surgery? A. They paid a little bit more than the regular open surgery, but not substantially. ...Q. And it sounds like Medicare and Medicaid pays a little more for laparoscopic or robotic surgery than for open surgery? A. Not for robotics. The robotics you get a flat rate of what the Medicare, Medicaid is. Q. And was that rate, from your recollection, the same as for a laparoscopic procedure? A. No. It was the same as the Medicare rate for open procedure.").

Burke (9/27/2022) Dep. Tr. 15:5-10 ("Q. Dr. Burke, when did you first join Valley Medical? A. August of 1984. Q. And at some point, you became the chairman of the department of surgery; correct? A. A couple of times, actually, yeah.").

Burke (9/27/2022) Dep. Tr. 25:9-25 ("Q. Was cost ever a factor in determining which modality you would use? ... [A.] Yes, I mean, that's why most of the gallbladder surgery was done laparoscopically versus robotically. Couldn't get the cost down. ...Q. What do you mean by you "couldn't get the cost down"? A. Well, the instruments on the Da Vinci were more expensive. The equipment that we used to perform a standard gallbladder operation were more expensive. And so the laparoscopic equipment, when analyzed by our hospital, was less expensive, and so that came into play. Plus we needed a higher level of technology."). See also Burke (9/27/2022) Dep. Tr. 26:1-24 ("Q. Who at the hospital performed the analysis to determine that the -- that the cost couldn't be brought down, I think you said? A. Well, we have an OR manager that looks at the data on -- almost on a monthly basis, and used procedures, whether it's gallbladder or colon or more advanced procedures. Q. So they would look at this on a per-procedure basis? A. Yes. Q. So some procedures you would decide to -- the hospital would decide to perform laparoscopically, but other procedures it may not? A. Well, the hospital didn't -- doesn't really make that decision, but at least they were trying to give us data to help us decide the appropriateness of the procedure. Q. And that data would vary by procedure-type? A. Yes, and by surgeon. Q. Why would it

100. The competitive impact of other types of surgery on da Vinci Surgical Systems is also reflected in data covering surgical procedures considered by Intuitive, where the company tracks its presence by comparing itself against laparoscopic and open surgeries using data under subscription from IQVIA. ²⁵⁴ Figure 1 below shows the rise of da Vinci surgery within the United States ²⁵⁵ over 2012-2021 using procedure volume data from IQVIA covering the specific categories of surgeries where da Vinci is cleared for use. As depicted in the figure, da Vinci's rise over this period coincided with a reduction in the portion of surgeries performed either laparoscopically or through open surgery.

vary by surgeon? A. Well, some surgeons would use more expensive equipment, either open laparoscopically or even robotically, to get a procedure performed.").

²⁵⁴ IQVIA is a leading vendor of healthcare data that estimates hospital-level procedures. *See* "About Us," IQVIA, accessed January 16, 2023, https://www.iqvia.com/about-us. *See also* "Real World Data Sets," IQVIA, accessed January 6, 2023, https://www.iqvia.com/solutions/real-world-evidence/real-world-data-and-insights. *See also* Intuitive-00014989 at -993 to -996

Dr. Lamb concludes that the United States is the relevant antitrust geographic market, basing this conclusion primarily on FDA's regulatory oversight regarding the marketing and sale of medical devices. Lamb Report ¶¶ 49, 68-69. I see no reason to disagree with his assessment that the United States should be the relevant focus for assessing the alleged conduct.

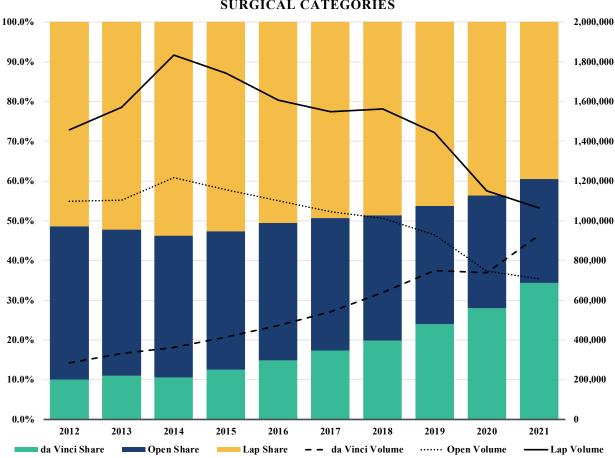


FIGURE 1
DA VINCI SHARE OF MINIMALLY INVASIVE AND OPEN SURGERIES FOR DA VINCI SURGICAL CATEGORIES

Sources and Notes:

Based on IQVIA data. The above figure is limited to the da Vinci procedural categories tracked by IQVIA. For making comparisons over time, the figure limits hospitals to those present in each year of the data from 2012 to 2021.

See Appendix A for discussion of the data preparation.

101. The apparent substitution to the da Vinci Surgical System from laparoscopy and open modalities, and in some cases, vice versa, is also evident from looking over time at the specific hospital level. I examined the relative shares of these three modalities over a ten-year period 2012-2021 for hospitals that used the da Vinci Surgical System as of 2021, including hospitals that were new to using it during the period. The details, which are presented in Appendix A, Table A-3²⁵⁶ can be summarized as follows:

²⁵⁶ Appendix A also shows the same calculations by IDN—relevant data patterns are similar.

- Among the 96 percent of hospitals that had an *increase* in da Vinci's share of procedures, including new da Vinci customers, the average increase in share was 37 percentage points, of which 19 percentage points came from laparoscopy and 18 percentage points came from open surgery.
- Among the 4 percent of hospitals that had a *decrease* in da Vinci's share of procedures, the average percentage point decrease in share was 11.5 percentage points, while laparoscopy increased by 12.5 percentage points and the share of open surgery decreased by 1 percentage point, on average.
- Approximately 0.4 percent of hospitals had neither an increase nor decrease in da Vinci's share.
- 102. The presence of laparoscopy and open surgery is also evident when looking within procedure category. Dr. Lamb provides a table in his report (his Table 1) showing the cleared types of surgery for the da Vinci. 257 I have taken Dr. Lamb's table and added procedure volumes from the IQVIA data for year 2021. I then summarize the relative proportions of procedure volumes by comparing the extent of procedures performed with the da Vinci Surgical System versus those performed through laparoscopic and open surgery. This is shown in Table 1 below. As indicated in the table, there is a significant presence of laparoscopic and open surgery within each surgical category where the da Vinci Surgical System is used to perform surgeries. These figures provide insight into Intuitive's competitive landscape from the perspective of the demand for its da Vinci Surgical System among both its customers and potential customers.

²⁵⁷ Lamb Report, ¶ 17, Table 1 "Approved da Vinci Surgical Procedures" based on Intuitive's website.

TABLE 1
AVERAGE MODALITY SHARE OF PROCEDURE CATEGORY, 2021

Category & Procedure Type	# of Hospitals Performing Procedure	% of These Hospitals Using da Vinci	da Vinci Share	Laparoscopic Share	Open Share
	[A]	[B]	[C]	[D]	[E]
Colorectal					
Colon	3,603	49%	23%	15%	62%
Rectal	1,733	59%	36%	12%	52%
General Surgery					
Bariatric	2,701	33%	16%	52%	32%
Cholecystectomy	4,209	42%	14%	80%	6%
Hernia	4,262	47%	23%	18%	58%
HPB	1,119	37%	18%	12%	70%
Foregut	2,784	53%	25%	73%	2%
Gynecology					
Hysterectomy	3,622	50%	33%	45%	22%
Thoracic	2,074	36%	19%	43%	38%
Urology					
Nephrectomy	2,215	62%	37%	33%	31%
Prostatectomy	2,055	70%	61%	29%	10%

Sources and Notes: Based on IQVIA data for 2021. "Cardiac" and "Head and Neck" are omitted because these categories are not tracked in the IQVIA data and account for less than 1 percent of all da Vinci procedures in 2021 based on Intuitive-00706097. "HPB" stands for Hepato-Pancreato-Biliary surgery, which involves surgery of the liver, pancreas and biliary system.

[A]: 4,452 total hospitals in the IQVIA dataset performed at least one surgery in 2021.

See Appendix A for discussion of data preparation.

103. The presence of laparoscopic and open surgery within the da Vinci's procedure categories is also evident when looking specifically at those hospitals that utilized the da Vinci Surgical System during 2021 (i.e., Intuitive's "customers"). As shown in Table 2 below, Intuitive's customers also are performing sizeable surgical volumes using these other modalities and, over time, the presence of other surgical modalities constrains Intuitive's market power. In addition, as I discuss in Section V below, these competitive constraints are also evident in Intuitive's pricing.

TABLE 2
AVERAGE MODALITY SHARE OF PROCEDURE CATEGORY AT DA VINCI HOSPITALS ONLY, 2021

Category & Procedure Type	# of Hospitals Performing Procedure	da Vinci Share	Laparoscopic Share	Open Share
	[A]	[B]	[C]	[D]
Colorectal				
Colon	2,015	41%	9%	51%
Rectal	1,380	45%	8%	47%
General Surgery				
Bariatric	1,813	23%	48%	28%
Cholecystectomy	2,054	29%	65%	6%
Hernia	2,066	48%	11%	41%
HPB	937	22%	11%	67%
Foregut	1,859	37%	61%	2%
Gynecology				
Hysterectomy	2,000	59%	27%	14%
Thoracic	1,566	25%	39%	36%
Urology				
Nephrectomy	1,698	48%	26%	26%
Prostatectomy	1,640	76%	18%	6%

Sources and Notes: Based on IQVIA data for 2021. "HPB" stands for Hepato-Pancreato-Biliary surgery, which involves surgery of the liver, pancreas and biliary system.

[A]: 2,076 total hospitals in the IQVIA dataset performed at least one da Vinci surgery in 2021. See Appendix A for discussion of data preparation.

104. The fact that laparoscopic and open surgeries competitively constrain Intuitive's pricing is illustrated in particular among benign and low acuity surgeries, such as cholecystectomies. An internal Intuitive document shows that I&A revenue per procedure is lower for procedure types with lower hospital reimbursements, where laparoscopic and open surgeries may be more attractive options for hospitals.²⁵⁸ To more effectively compete, Intuitive introduced extended use Xi EndoWrist instruments aimed at reducing the costs of instruments per procedure and

²⁵⁸ Intuitive-00014989 ("Procedure Prioritization") at -997.

making robotic surgery even more attractive to hospitals using all three surgical modalities.²⁵⁹ In addition to the Extended Use programs, Intuitive lowered the price of certain instruments that are most commonly used in lower acuity procedures and/or lower reimbursed procedures.²⁶⁰

- 105. The above evidence supports a surgical solutions marketplace in which Intuitive's surgical system is one among other competitive options for hospitals and where Intuitive is particularly focused on competition with its closest substitutes—laparoscopic and open surgeries—consistent with Intuitive not being positioned to exercise monopoly power.
 - F. DR. LAMB'S ASSERTION THAT INTUITIVE'S MARGINS REFLECT MONOPOLY POWER IS NOT SUPPORTED BY THE EVIDENCE HE PROVIDES
- 106. Dr. Lamb states that "another way of determining whether a firm possesses market power is by looking for the actual *exercise* of market power in the form of higher prices." After a cursory review of materials, he then concludes that Intuitive's pricing and margins reflect monopoly

Intuitive-00687060 at -063 ("Reducing the price-per-use for da Vinci X/Xi instruments commonly used in these procedures makes the benefits of da Vinci surgery more achievable, at a cost more in line with the cost of laparoscopic procedures.").

Tourand (11/4/2022) Dep. Tr. 134:1-23 ("Q. Do I understand that if the lives were increased by 50 percent from 10 to 15 and the price of the instrument were increased by some percentage less than 50 percent, that the customer would receive some portion of the savings but not 100 percent of the savings?...[A.] That is correct. It's a complex -- it's more -- more complex than it needs to be in that example. If you don't change the price of the existing instrument at 10 uses, but you increase the number of uses, then the price per use goes down. The customer then receives 100 percent of the benefit. On the other -- on the other side, if you increase the uses and you keep the price per use the same, the instrument list price increases, and Intuitive receives all the benefit. So the program was designed to reduce the price per use of the da Vinci X and XI instrument and share in that Extended Lives Program benefit with the customer.").

²⁶⁰ Intuitive Surgical, Inc., 2021 10-K at p. 59. These reduced pricing instruments include medium/large clip applier, permanent cautery hook, permanent cautery spatula, and round tip scissors. *See*, e.g., Intuitive-00560028 at -038.

²⁶¹ Lamb Report, ¶ 99 (emphasis in original).

power in his tying market (his market for MIST Surgical Robots). ²⁶² Dr. Lamb provides no direct evidence or analysis to support this claim. Moreover, the limited pieces of information he does point to—such as accounting margins for individual business segments that are measured using the "cost of goods sold"—are not only irrelevant to such an inquiry, these pieces omit the costs of Intuitive's numerous investments that are fundamental to consider and which Dr. Lamb discusses at length elsewhere in his report as being important to Intuitive's success.

- 107. To support his claim that Intuitive possessed monopoly power in the asserted tying market, Dr. Lamb cites to an Intuitive document showing that its systems business unit earned "contribution margins" of 65 percent and 60 percent worldwide in 2019 and 2020, respectively. He concludes that if Intuitive had not "dominated" the asserted tying market, "it would not have been able to raise prices so far above marginal cost to supra-competitive levels and earn the supranormal profits it earned on its da Vinci surgical robot." Dr. Lamb's analysis is incorrect as a matter of economics and fact.
- 108. It is by design that a company's contribution or variable margins focus exclusively on costs that vary over a short time frame and do not consider other important costs of bringing a product to market, such as those of research and development. Such costs factor into a company's strategic decision making over a longer time horizon. It is well-accepted by economists that an assessment of a company's profits in relation to monopoly power should consider the investment costs associated with developing the company's products, the timing of those investments, as well as the riskiness of these investments under uncertainty. Thus, Dr. Lamb's use of

²⁶² Lamb Report, ¶¶ 106-107.

²⁶³ Lamb Report, ¶ 102.

²⁶⁴ Lamb Report, ¶ 102.

For a discussion of why "variable margins" can lead to "serious biases" in measuring a company's returns, see, e.g., Dennis W. Carlton and Jeffrey M. Perloff, Modern Industrial Organization, Fourth Edition (Boston: Pearson Education, Inc., 2015) at p. 278, who state "That is, they tend to ignore capital, research and development, and advertising costs. This approach may lead to serious biases."

²⁶⁶ See, e.g., Franklin M. Fisher and John J. McGowan, "On the Misuse of Accounting Rates of Return to Infer Monopoly Profits," *American Economic Review* 73, No. 1 (1983): 82-97.

- contribution margins to attribute monopoly power to Intuitive is both inappropriate and inconsistent with economic practices.
- 109. To better understand the importance of Intuitive's investment costs on its strategic investment and pricing decisions, consider the following simplified example.
 - A medical device company, Deviceco, considers an investment in an innovation that
 potentially could revolutionize minimally invasive surgery and generate significant benefits
 for surgeons and their patients. But, the practical and commercial viability of the investment
 is uncertain. A priori, it has only a 10 percent chance of success.
 - Deviceco must make an investment of \$10 million to generate the innovation.
 - The innovation is a huge success! Deviceco sets its prices, as it had planned, to earn a profit of \$100 million.
- 110. Dr. Lamb's analysis of the above example might say those profits are too large: Deviceco is earning \$100 million on only a \$10 million investment, a return of 900 percent! Deviceco must be a monopolist. But, this ignores the fact that when Deviceco made its investment in competition with other surgical systems and modalities it was a breakeven proposition (i.e., the 10 percent chance of obtaining anticipated profit of \$100 million yields an expected value of \$10 million, which is equivalent to the cost of Deviceco's investment). Moreover, such an analysis also is missing any acknowledgment of the predictable adverse effect on Deviceco's investments its inability to earn such returns would have.
- 111. Ironically, while ignoring the economic costs of innovation as it relates to alleged monopoly power, Dr. Lamb appears to recognize that Intuitive's ability to win customers and compete effectively over time has depended on its historical and ongoing innovation in its efforts to create and improve the quality of the da Vinci Surgical System in relation to other competing options. As Dr. Lamb details in his report, Intuitive historically incurred significant research, development, and other costs over time in the development of its da Vinci Surgical Systems. For example, he discusses the "high capital costs associated with research and development" as well

as "the length of time" necessary to "bring [a robotic solution] to the market and compete effectively." ²⁶⁷

112. Dr. Lamb also describes Intuitive's ongoing product development activities and recurring investment across a number of dimensions. For example, quoting from recent investment analyst commentary, he highlights Intuitive's existing portfolio of patents and continual investment into improving its systems. He states:

"From a regulatory standpoint, [Intuitive] has been issued or owns over 2,900 patents and has more than 1,900 active patent applications. Competing products would need to meet the quality standards of [Intuitive's] product offerings to be able to come to market. This represents a substantial hurdle for competitors, as [Intuitive] continually improves its systems." ²⁶⁸

Similarly, and again quoting from recent investment analyst commentary, Dr. Lamb recognizes the value of Intuitive's ongoing investment. He points out that Intuitive "continues to invest heavily in R&D and has seen its R&D budget triple over the past 5 years." ²⁶⁹

- 113. As I discuss in Section VII.C below, Intuitive has faced significant economic costs of innovation over time. Moreover, as discussed above, one aspect of Intuitive's innovation has involved the development of four generations of surgical systems that have become available to customers over time. Intuitive's continued investment, as recognized by Dr. Lamb, is inconsistent with the behavior of a monopolist operating in a world absent competition.
- 114. Evidence also indicates that risk—which Intuitive breaks into "four core risk buckets" including "[c]linical risks," "[t]echnical risks," "[r]eimbursement & [r]egulatory risks," and "[c]ompetition risk"—factors into Intuitive's investment decisions.²⁷⁰ In an accompanying workbook to

Lamb Report \P 90.

 $^{^{268}}$ Lamb Report ¶ 91, quoting an Enlightened Capital publication.

²⁶⁹ Lamb Report ¶ 90, quoting an Enlightened Capital publication.

²⁷⁰ Intuitive-01172899 ("Long-term opportunity portfolio assessment," November 6, 2020) at -902.

Intuitive's 2020 presentation titled "Long-term opportunity portfolio assessment," Intuitive calculates values adjusted for "Risk and Strategic Benefit" and ranks opportunities based on assessments of various factors, including risk.²⁷¹

115. Intuitive committed to its business model up front to ensure quality and cover investment costs under uncertainty. 272 As documented in its early business plans, Intuitive entered the market as an alternative to laparoscopic or open surgical solutions. 273 Given that this business model long predates the entrance of SIS and was developed when the competitive landscape was primarily open and laparoscopic surgical modalities, Intuitive's actions are not a demonstration of market power, but rather reflect a go-to market strategy against existing solutions.

G. DR. LAMB'S EVIDENCE OF A SSNIP TEST IS INAPT AND DEMONSTRATES THAT INTUITIVE IS NOT PRICING AS A MONOPOLIST

116. The "hypothetical monopolist" or "SSNIP" test for market definition is a concept that typically is applied in the evaluation of horizontal mergers. It is well understood by economists that the SSNIP test, although useful as an organizing concept for market definition, generally is not as

²⁷¹ Intuitive-01172908 ("Opportunity portfolio assessment_v50.xlsx"), tab "Project_Ranking Tool."

DeSantis (in *Restore*) Dep. Tr. 48:10-19 ("Q. Why hasn't Intuitive just lowered its prices for the new EndoWrist instruments to address the need from customers for lower prices? A. ...[w]e've never raised prices. We haven't lowered them. We -- We take the earnings, reinvest them into making better products for the surgery, so that's, you know, essentially been our model."). A document describing Intuitive's business plan dated 1995 describes various characteristics of the Resposable Transmission Unit ("RTU"). Specifically, it states, "During the design phase, the company will work closely with its patent attorneys to insure that the interface design ... between RTU and disposables, have ironclad design patentability. This will secure ... that other manufacturers will be unable to manufacture unauthorized and possibly dangerous RTUs and disposables." Intuitive-00595673 at -682.

²⁷³ Intuitive-00595673 at -677-678.

straightforward to apply in monopolization cases.²⁷⁴ This is because, if, for example, Intuitive possesses monopoly power, it already should be pricing as a monopolist would, and thus could not profitably impose a SSNIP on its customers regardless of what company it merges with. This is known to economists and antitrust practitioners as the "cellophane fallacy."²⁷⁵

117. I did not find a SSNIP test in Dr. Lamb's report. Instead, Dr. Lamb presents testimony purporting to show that Intuitive could impose a SSNIP on its current customers.²⁷⁶ For the reasons provided in the previous paragraph, this is not evidence of a proper SSNIP test. In fact, this evidence is inapposite to a proper SSNIP test—to the degree that it indicates anything, it indicates that Intuitive is *not* currently pricing as a monopolist would.

V. INTUITIVE'S PRICING IN PLAINTIFF'S ASSERTED "TIED" MARKET DOES NOT REFLECT THE ABUSE OF MONOPOLY POWER

118. As I explained above, Dr. Lamb's analysis of Intuitive's alleged monopoly power involves a tautological assertion that Intuitive has monopolized a "tying" market for a product that

See, e.g., Lawrence J. White, "Market Power and Market Definition in Monopolization Cases: A Paradigm Is Missing," in Wayne D. Collins, ed., Issues in Competition Law and Policy, American Bar Association, 2008.

See, e.g., Gregory Werden, "The History of Antitrust Market Delineation," Marquette Law Review 76, No. 1 (1992): 123-215. In discussing the well-established economic critique known as "cellophane fallacy" regarding the Supreme Court's error in evaluating "the cross-elasticity of demand at the monopoly price" during the Cellophane case, the article states "A rational monopolist raises price until competition from other products makes further increases unprofitable. At that point, there are likely to be significant cross-elasticities of demand with other products, but they are entirely irrelevant to the question of whether the firm possesses market power. The relevant question for assessing the firm's market power is whether the cross-elasticities of demand were so great near competitive price levels as to prevent a significant elevation of prices above the competitive level in the first instance" (p. 139).

Specifically, Dr. Lamb supports his conclusion based on the responses made by two hospital executives in response to a question at their depositions regarding whether higher hypothetical prices for the da Vinci Surgical System would have changed their hospital's behavior. Lamb Report ¶¶ 31-32.

effectively only it sells.²⁷⁷ In addition, Dr. Lamb claims that Intuitive has charged supracompetitive prices.²⁷⁸ I explained above that Dr. Lamb's purported evidence of supracompetitive prices is inapposite because it does not consider that Intuitive must earn positive gross margins to support its procompetitive and pro-consumer innovations.²⁷⁹

- 119. In addition, as a matter of economics, it would have been illogical for Intuitive—when it first began marketing da Vinci Surgical Systems—to charge supracompetitive prices and impose anticompetitive tying arrangements as it initially fought to gain a toe-hold in the broader market for surgical solutions against well-established alternatives such as traditional open and laparoscopic surgeries. That is, surely Intuitive did not act as a monopolist before it gained *any* significant sales.
- 120. Based on this economic logic, one way to evaluate whether Intuitive has been imposing supracompetitive prices and anticompetitive contract terms is to determine the extent to which Intuitive has changed its competitive behavior as it has grown. As I noted above, Intuitive always has competed by selling the components of its surgical system together. Moreover, the analyses presented in this section, as further described below, show that (i) Intuitive's platform prices have not increased; (ii) prices for instruments have not increased; and (iii) there is no evidence of price discrimination across customers. Hence, Intuitive's pricing behavior has not reflected an exercise of monopoly power.

A. INTUITIVE'S PLATFORM PRICES HAVE NOT BEEN INCREASING OVER TIME

121. In Figure 2 below, I show average selling prices for the da Vinci model Xi over the period 2014 to 2021, among U.S. customers who purchased the platform. This model accounted for 93 percent of the sales revenue from platform purchases during the period, and it was the only model that was sold in every year of this period. As shown in the figure, da Vinci platform prices

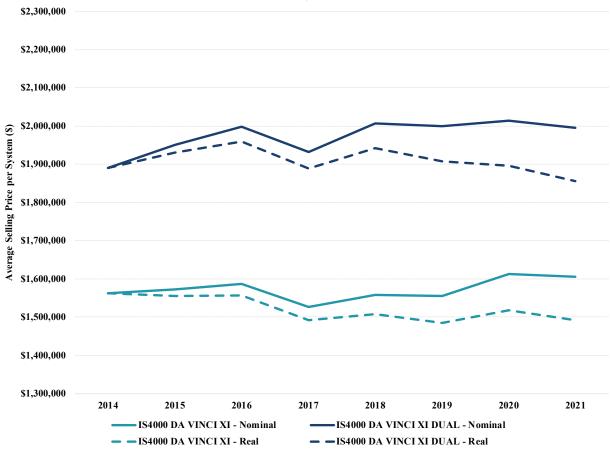
²⁷⁷ See Section IV.D above.

²⁷⁸ Lamb Report, ¶ 102.

²⁷⁹ See Section IV.F above.

for both Dual and Single console Xi models were relatively flat during this period—increasing slightly on a nominal basis and decreasing slightly in real terms.

FIGURE 2 AVERAGE SELLING PRICES FOR THE DA VINCI MODEL XI, SINGLE AND DUAL CONSOLE, 2014-2020



Sources and Notes: Based on Intuitive's System Sales data. Current dollars are converted to constant 2014 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). See Appendix A for discussion of data preparation.

B. INTUITIVE'S INSTRUMENT PRICES HAVE NOT BEEN INCREASING OVER TIME

122. As an initial observation, Intuitive's instrument pricing does not appear to differ within the same period for customers who have purchased the same instrument (as defined by the "product"

number). ²⁸⁰ For example, when looking across all of Intuitive's instruments sold during 2021, on average, 96 percent of customers paid the same price for the specific instrument. Although the mixture of instruments purchased can and does typically vary between customers due to the specific instrument needs of their surgeries, prices for particular instruments generally show limited variation across customers during a given year. ²⁸¹ Hence, to account for the possibility that Intuitive increased prices in a discriminatory way by raising the prices of frequently used instruments or on instruments used in high-volume procedures, I examine pricing using alternative lenses. For my initial assessment, I evaluate instrument prices on a "per-procedure" basis after combining the detailed procedures data together with Intuitive's "net sale" amounts from instrument sales transactions for the customer over a particular year. ²⁸²

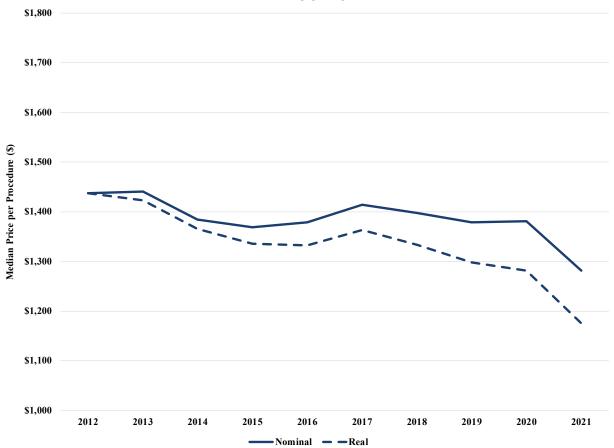
123. Figure 3 shows this comparison of instrument prices over time when using the metric of price per procedure. Here each line shows the trend in median price paid among customers during the calendar year, and I show these prices both with and without adjusting for inflation (separate lines are shown for "real" versus "nominal"). Both lines in the chart indicate that prices have not risen over time. Neither trend is indicative of an exercise of monopoly power.

The specific field in Intuitive's Instrument and Accessories data is called "product," which is a six-digit product number typically along with a two-digit suffix. For a discussion of the data preparation involved in this analysis, see Appendix A.

When looking across years, the composition of particular instruments sold might change over time due to changes in the prevalence of "single-use" instruments or due to changes in the frequency of sales for particular instruments after Intuitive's recent Extended Use Program.

²⁸² See discussion under Data Preparation in Appendix A.

FIGURE 3
MEDIAN ANNUAL DA VINCI INSTRUMENT PRICES FOR U.S. CUSTOMERS, EXPRESSED PER PROCEDURE



Sources and Notes: Prices per procedure relate net sales amounts calculated from Intuitive's I&A sales data to Intuitive's procedures data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). See Appendix A for discussion of data preparation.

124. These findings are also confirmed when I examine the price of instruments over time when measured on a per-use basis.²⁸³ For this assessment, I measure prices by relating Intuitive's "net sale" amounts from instrument sales to its recorded number of uses for each instrument.²⁸⁴

See Figure A-3 in Appendix A. I use a regression analysis to control for changes in the composition of individual instruments sold across customers in a given year, and the results of the analysis confirm that prices have not risen over time. See Table A-1 in Appendix A. I also include a regression analysis where I look only at prices for instruments sold for the S/Si models only. See Table A-2 in Appendix A.

²⁸⁴ See discussion under Data Preparation in Appendix A.

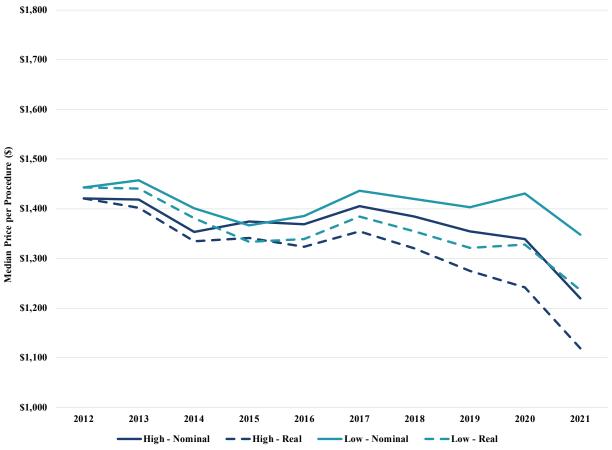
C. INTUITIVE HAS NOT BEEN PRICE DISCRIMINATING AGAINST ANY GROUP OF CUSTOMERS

- 125. As an additional examination, I look at whether there is evidence of apparent price discrimination against customers that plausibly are more dependent on the da Vinci Surgical System (i.e., groups that perform a large proportion of da Vinci-eligible procedures using the da Vinci Surgical System). Such evidence could indicate an exercise of monopoly power.
- 126. In this initial analysis, I divide Intuitive's customers into two equally-sized groups (a "high" group and "low" group) based on the da Vinci Surgical System's relative share of procedures at each hospital during 2021. The group determinations are made using the IQVIA data for the da Vinci procedures covered in Table 1 above. ²⁸⁵ I then examine whether instrument prices for the high-share group are materially higher than the low-share group's prices, by comparing prices for these two groups within the same year. I also examine whether the price trends shown in the preceding section, which are measured across all customers, do not hold for either of these two groups of customers.
- 127. Figure 4 below shows this comparison using prices expressed per procedure. As shown in the figure, the customer price per procedure for the high-share group is generally at or below the price for the low-share group. It is also evident that the two groups experience similar price trends during the period. Trends shown in Figure 4 are not indicative of an exercise of monopoly power.

79

The data for each customer are aggregated to the IDN level ("Integrated Delivery Network") where hospital entities that are related under common ownership or a group purchasing affiliation are combined. *See* discussion in Appendix A.





Sources and Notes: Prices per procedure relate net sales amounts calculated from Intuitive's I&A sales data to Intuitive's procedures data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the median da Vinci share of total procedures of 40 percent.

VI. SIS HAS NOT BEEN PREVENTED FROM COMPETING IN THE MANY LEGITIMATE MARKETS FOR MEDICAL EQUIPMENT MAINTENANCE AND REPAIR

128. The majority of SIS's revenues comes from legitimate medical device repairs, which it can continue to perform. In this section, I describe the many legitimate medical instrument repair and replacement markets where SIS can and does currently compete and provide evidence that SIS has not been foreclosed from competing in this industry.

A. MEDICAL EQUIPMENT REPAIR SERVICES INCLUDE MANY SALES OPPORTUNITIES FOR INDEPENDENT SERVICE ORGANIZATIONS

- 129. The size of the industry for medical equipment repair and maintenance is estimated to be \$4.1 billion in US annual revenue in 2021. 286 Approximately 24.6 percent of that revenue is captured by independent service organizations ("ISOs"), as opposed to original equipment manufacturers ("OEMs") that capture the other 75.4 percent. Reasons why OEMs tend to have a larger share of repairs may include: (1) manufacturers' knowledge of the equipment that allows them to "have better access to parts, trained technicians and the necessary tools;" (2) proprietary information about the equipment held by the manufacturer; and (3) registration of the repairs with regulatory bodies, such as the FDA, that "allows customers to better track deficiencies." Prices charged by OEMs tend to be higher than those charged by ISOs, though customers may choose OEMs more often when the capital is available because of the "highly-regulated nature of medical equipment and the potential loss of life associated with poor repairs." 289
- 130. Although OEMs commanded more than three-quarters of revenues from repairs, ISOs collectively received approximately \$1 billion in revenue for medical equipment repairs and maintenance.²⁹⁰ Customers tend to seek ISOs to service "less technical machinery like endoscopes"²⁹¹ and older equipment as OEMs may have "[shifted] their focus away from their older models."²⁹²

Jack Curran, "Medical Equipment Repair & Maintenance Services," Industry Report OD4964, IBISWorld, December 2021 at p. 11 ("Curran").

²⁸⁷ Curran at p. 17-18.

²⁸⁸ Curran at p. 17.

²⁸⁹ Curran at p. 18.

 $^{^{290}}$ \$4.1 billion x 24.6 percent = \$1.0086 billion.

²⁹¹ Curran at p. 18.

²⁹² *Id*.

B. SIS CAN AND DOES COMPETE IN MANY LEGITIMATE MARKETS FOR THE REPAIR OF MEDICAL EQUIPMENT

- 131. Founded in 1971, SIS is a "surgical instrument and device repair"²⁹³ company whose services include instrument restoration, rigid endoscope repairs and rebuilds, semi-rigid endoscope restoration, flexible endoscope servicing, video system servicing, power equipment repairs and rebuilds, as well as other specialty repair services.²⁹⁴ Since 2013, SIS's annual revenues have ranged from \$7.5 million in 2013 to \$10.7 million in 2020.²⁹⁵ According to Mr. Johnson, SIS's "main competitors in its business" are STERIS IMS and AgilityHealth,²⁹⁶ and the three companies (SIS, STERIS IMS, and AgilityHealth) "manage" around 90 percent of "all the opportunities for instrument and device repairs in hospitals in the U.S."²⁹⁷ After factoring in "hospitals that don't work with independent organizations," Mr. Johnson estimated that the "portion of the services [] provided by SIS, STERIS IMS, or [AgilityHealth] would be 50 percent."²⁹⁸
- 132. SIS sold its first reset EndoWrist instrument on June 28, 2019.²⁹⁹ Between June 28, 2019 and December 10, 2019, SIS sold 41 reset EndoWrist instruments and received \$38,900 to \$55,700 in revenues, which would be 0.56 to 0.80 percent of its total revenue in 2019.³⁰⁰ Throughout this

²⁹³ "About Us," Surgical Instrument Service Company, accessed January 3, 2023, https://sis-usa.com/about/.

²⁹⁴ "Services," Surgical Instrument Service Company, accessed November 17, 2022, https://sis-usa.com/services/.

²⁹⁵ SIS320922 (SIS's 2020 Income Statement). SIS279094 (SIS's 2013 Income Statement). SIS reported \$10.1 million through October 2021. SIS327629.

²⁹⁶ Johnson 30(b)(1) (10/27/2022) Dep. Tr. 9:5-10.

²⁹⁷ Johnson 30(b)(1) (10/27/2022) Dep. Tr. 11:3-15.

²⁹⁸ Johnson 30(b)(1) (10/27/2022) Dep. Tr. 13:13-14:8.

²⁹⁹ SIS000167.

In my damages report, I calculated that SIS sold 41 resets and received \$55,700 in revenue associated with those sales; *see* Smith Counterclaims Damages Report, Table 1. Mr. Bero, SIS's damages expert, claims that SIS sold 42 resets and received \$38,900 in revenues; *see* Bero Report, tab "14.0" in "Bero Natives.xlsx." The reason for the difference in our counts of resets is that Mr. Bero includes an undated sale of a reset to Advocate Good Samaritan, which I omitted from my analysis (*see* Smith Counterclaims Damages Report at ¶46 and

period, SIS served as a distributor for Rebotix, who owned the Interceptor "technology" and performed the EndoWrist reset "service." Rebotix compensated its distributors, including SIS, by a set fee per reset EndoWrist instrument. 302

133. Although SIS stopped selling reset EndoWrist instruments in December 2019, SIS's annual revenues continued to increase through 2022. 303 Mr. Posdal stated that SIS's business outside of EndoWrist resets has not been negatively affected by its inability to sell the resets. 304

VII. INTUITIVE'S CONDUCT HAS LEGITIMATE BUSINESS JUSTIFICATIONS

- 134. Even if one considers the components of a surgical system (such as Intuitive's da Vinci Surgical System) as "distinct" products, standard economic principles explain why selling the components as an integrated product or "bundle" can benefit consumers. These include:
 - a. Bundling can insure the supplier against risk, including risks to patient safety, particularly when uncontrolled third parties do not have the same incentives as the supplier to preserve product reputation.

compare with row 50 on tab "14.0" in "Bero Natives.xlsx"). Regarding our difference in revenue, Mr. Bero did not include revenues for certain sales to Kaiser Fontana dated August 27, 2019 and Marin Health Medical Center dated November 15, 2019.

SIS320176 (SIS's 2019 Income Statement). SIS's total revenue in 2019 was \$6,996,108. 0.56 percent equals 38,900 divided by 6,996,108 times 100 percent; 0.80 percent equals 55,700 divided by 6,996,108 times 100 percent.

³⁰¹ See Section II.D.2 above.

³⁰² *Id.* Evidence indicates that SIS's price sheet matches with Rebotix's price list for distributors; *see* SIS010647 and REBOTIX040277.

³⁰³ SIS320922 (SIS's 2020 Income Statement); SIS327629 (SIS's 2021 Income Statement through October 31, 2021). Mr. Posdal estimated that SIS's 2022 annual gross revenue would be \$18 million. Posdal 30(b)(1) (11/1/2022) 15:23-25.

Posdal 30(b)(1) (11/1/2022) 64:22-65:12 ("Q. Okay. Did SIS's inability to move forward with the reset business impact its reputation at all? A. Separate from our existing service, I don't believe so. Q. What do you mean separate from your existing service? A. Well I – I think that any question of our ability to service the EndoWrists had no impact on the – the existing services we were providing in a negative way. Q. Okay. So there was – there was no negative impact from the inability to – to provide the EndoWrist services on the rest of SIS's business; is that right? A. I think that's correct.").

- b. The insurance against risks that "bundling" provides can create (and preserve) incentives for innovation.
- c. Bundling complementary products can reduce costs for the consumer.
- 135. This section shows that by selling an integrated product (or a "bundled" product if the components are deemed to be "distinct"), Intuitive is able to achieve these procompetitive objectives. I first provide an overview of the economics of bundling with an emphasis on when bundling promotes procompetitive benefits to patient safety and innovation. I then explain how Intuitive's product design and business practices mitigate risks, including risks to patient health, and promote ongoing innovation. Finally, I explain how Intuitive is offering consumers a superior financial deal by selling a system rather than individual components. As a corollary to this analysis, I explain why SIS's purported savings are misleading, particularly after accounting for increased risks to patient safety.

A. BUNDLING HAS PROCOMPETITIVE JUSTIFICATIONS

136. Two related economic concepts that arise in the discussions about packaged or integrated products are "bundling" and "tying." Bundling is the "[p]ractice of selling two or more products as a package." For example, cable networks often sell a menu of channels as a package. Tying is the "[p]ractice of requiring a customer to purchase one good in order to purchase another." The distinction between tying and bundling is that in the case of tying the

³⁰⁵ In the context of this case, the economic arguments for "tying or "bundling" equally apply to "exclusive dealing." By entering into the SLSA with Intuitive, customers acknowledge that they will not allow unauthorized third parties to "modify, disassemble, reverse engineer, alter, or misuse" any component of the da Vinci Surgical System (*see* ¶70.a above). This contractual arrangement effectively "bundles" the components of the system.

³⁰⁶ Pindyck and Rubinfeld at p. 419. Economists also use the terms "pure bundling" and "mixed bundling," where "pure bundling" refers to two or more products that are only offered together and "mixed bundling" are two or more goods are sold together and also separately. *See*, e.g., Pindyck and Rubinfeld at p. 423.

³⁰⁷ Pindyck and Rubinfeld at p. 426.

³⁰⁸ Pindyck and Rubinfeld at p. 428.

tied product is available for sale on its own, whereas bundled products always are sold together. ³⁰⁹ Because the components of the da Vinci Surgical System (particularly the da Vinci platform and EndoWrist instruments) are essential to the function of the overall system and are sold through the same contractual arrangement, the da Vinci Surgical System is more properly described as a bundle. However, as a matter of the relevant economics here, the distinction between bundling and tying is inconsequential.

- 137. In his "primer" on tying cases, Professor Jean Tirole (winner of the Nobel Prize in Economics in 2014 "for his analysis of market power and regulation" names six "rationales other than anticompetitive ones" as to why a firm may choose to tie two of its products, one of which is a monopoly product "M" (tying product) and the other a potentially competitive product "C" (tied product): 311
 - a. Tying saves on "transaction costs" for the consumer, who would otherwise need to make additional choices or seek components from additional sources;
 - b. Tying reduces "compatibility costs" for the manufacturer, who otherwise would need to incur costs to ensure interoperability between its product(s) and those of other manufacturers;

Jean Tirole, "The Analysis of Tying Cases: A Primer," *Competition Policy International* 1, No. 1 (2005): 8 ("The difference between tying and pure bundling is that the tied product is available on a stand-alone basis under tying, but not under pure bundling. This distinction however is inconsequential if, as we assumed for illustrative purposes, the tied product is valueless without the tying product.") ("Tirole").

³¹⁰ "Jean Tirole – Facts," The Nobel Prize, accessed January 6, 2023, https://www.nobelprize.org/prizes/economic-sciences/2014/tirole/facts/.

The rationales listed in this paragraph are based on Tirole at pp. 14-17. *See* Tirole at p. 4 for his terminology of the monopoly and potentially competitive products. The rationales listed in Tirole show that even if a firm owns a "monopoly" product that it sells in combination with another product, the firm may have rationales other than anticompetitive ones for doing so. This should not be misinterpreted as an indication that Intuitive has monopoly power over any product, which, as I have explained in Sections III-V, it does not.

- c. Tying allows manufacturers to "protect M's reputation vis-à-vis consumers or to insulate M against assignment of liability when a product malfunctions because of an independent producer's poor design;"³¹²
- d. Tying may prevent leakage of "proprietary information embodied in the design of the M product, such as information about general purpose functionalities that naturally lie in product M rather than the complementary product C;"
- e. The low cost of C (viewed as being tied to M) may be a "legitimate price response" in certain situations, such as encouraging consumers to try a new "product with unknown quality;" and
- f. Tying may be an efficient way to "[meter]... demand and prices to depend on customer usage," such that customers with relatively lower willingness to pay for M would not be excluded.³¹³
- 138. Although several of these factors are relevant to Intuitive's business practices, as discussed below, evidence indicates that one of the most important reasons for Intuitive's challenged conduct relates to item (c) above—selling the da Vinci Surgical System as an integrated product allows Intuitive to maintain strict control of the components that are used with its system, which

Professor Tirole further explains, "A tie can then be viewed as solving a problem of moral hazard in teams when third parties (such as consumers or the courts) do not have the technical expertise or the information necessary to know who is at fault." *See* Tirole at p. 15.

Tirole at p. 16. It is worth acknowledging that, in the article, Professor Tirole also describes scenarios in which tying may serve to either "monopolize the competitive market" or "protect its monopoly position in the monopoly segment" (Tirole at p. 17). Regarding the first point, tying may be an attempt to monopolize the competitive market when it forecloses a portion of C from rival companies, namely the consumers who demand the bundle of M and C products. Regarding the second point, tying may be a means to protect the company's monopoly over product M when it discourages entry in M because of the lack of competition in C. In this case, the Plaintiff alleges that Intuitive is attempting to monopolize effectively C by foreclosing customers who demand the bundle, which would be all customers since the components of Intuitive's surgical system only function as a system. I do not find this scenario to be applicable with respect to Intuitive's conduct because (1) Intuitive does not possess the "monopoly power" in the tying market to foreclose the alleged market (see Section IV above) and (2) SIS has not been foreclosed from legitimate markets for medical equipment repair (see Section VI above).

protects patient safety, as well as Intuitive's reputation and financial viability.³¹⁴ I discuss this feature of Intuitive's conduct in more detail in the next section.

B. INTUITIVE PROTECTS PATIENTS BY SELLING AN INTEGRATED PRODUCT

are essential for Dr. Lamb's anticompetitive theory of harm, Intuitive's challenged conduct would be justified even if discrete antitrust markets for the components of the da Vinci Surgical System were deemed to exist. For example, the integrated system design allows manufacturers to avoid a potential "principal-agent problem," which is a well-known concept in economics when misaligned incentives can lead to undesirable outcomes. 315 The principal-agent problem arises when the agent (e.g., a third-party company) chooses actions to its own benefit instead of actions that achieve the goals of the principal (e.g., the OEM). 316 In the context of medical equipment repairs, the OEM has strong incentives to maintain the quality of its product—particularly with respect to patient safety—given the risks of reputational harm and financial losses. 317 A third-party company may not have the same incentives or ability to protect the product reputation and quality for reasons such as (i) it does not have as much at stake if something goes wrong, (ii) it has lower costs of switching to other devices if its services go awry, and (iii) it lacks the technical knowledge to know when repairs could damage the device. Although the economics literature has proposed ways that may address the principal-agent problem, these remedies can be

See James D. Dana Jr. and Kathryn E. Spier, "Bundling and quality assurance," The RAND Journal of Economics 49, No. 1 (2018): 128-154 (e.g., "This article argues that bundling may be necessary to assure the quality of experience goods when monitoring is private and imperfect" at p. 129).

³¹⁵ See Pindyck and Rubinfeld at pp. 645-651.

³¹⁶ Professors Pindyck and Rubinfeld describe the principal-agent problem as follows: "A principal-agent problem arises when agents pursue their own goals rather than the goals of the principal" (Pindyck and Rubinfeld at p. 646).

For example, in the U.S., adverse events associated with medical devices are reported to the FDA and publicized on the FDA's website; *see* "MAUDE – Manufacturer and User Facility Device Experience," U.S. Food and Drug Administration, accessed January 6, 2023, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm ("MAUDE").

costly and inefficient for the OEM.³¹⁸ By creating an integrated product, the OEM may be able to avoid having to monitor and enforce stringent standards on potential third parties to ensure that its product remains at the highest quality.

140. Intuitive faces a principal-agent problem where third-party companies and healthcare providers do not have the same incentives as Intuitive to ensure the highest level of patient safety and thereby preserve and enhance the da Vinci brand. By selling an integrated system, Intuitive maintains a measure of control over the clinical quality provided by the da Vinci Surgical System, protecting patients from malfunctions and protecting Intuitive's reputation and financial viability in the process.

1. Patients and surgeons benefit from Intuitive's best product and likely outcomes

141. As I discuss in more detail below, evidence shows that patients and surgeons rely on Intuitive to ensure that the da Vinci Surgical System will perform at high safety and technical standards, and Intuitive has invested in building this trust with its customers and the medical community.

For example, *see* Jeffrey M. Perloff, *Microeconomics, Seventh Edition* (Boston: Pearson Education, Inc., 2015), 653-671 (on the principal-agent problem). Monitoring may be "counterproductive or not cost effective" for some jobs (at p. 666). Contracting may entail a trade-off between "increasing production efficiency while reducing risk-bearing efficiency," and "when the parties find that they cannot achieve both efficiency in production and efficiency in risk bearing, they choose a contract that attains neither" (at pp. 658, 664).

Because the Plaintiff in this matter (SIS) is a third-party company, I focus my discussion on Intuitive's relationship with such companies.

Intuitive also faces a principal-agent problem with healthcare providers (Intuitive's direct customers). After entering into the SLSA with Intuitive, certain healthcare providers may wish to reduce their costs by purchasing reset instruments from third parties without Intuitive's approval to increase their profits, since the payment that they receive for the surgery is determined by negotiations with health insurers. However, healthcare providers do not internalize how the increase in patient risk from the resets would negatively impact Intuitive's reputation with the medical community, regulators, and patients in the case of an adverse event. The contractual agreements in Intuitive's SLSA explicitly address this agency problem.

142. Evidence indicates that surgeons depend on Intuitive to ensure that the da Vinci Surgical System will perform with the precision necessary for successful procedures. Surgeons have expectations over the "performance characteristics" of the surgical instruments that they use. 320 Examples of such characteristics in an EndoWrist instrument include "motion fidelity," "sharpness of the blades," "strength of holding a needle," and "alignment... between the jaws." 1 If the instrument is not performing to the surgeon's expectations, the surgeon would need to replace the instrument during the procedure and return the potentially defective instrument to Intuitive. 1 Intuitive has testified to its "commitment to the quality and to patient safety" 2 and that surgeons can trust the safety of the instrument because of Intuitive's rigorous testing. 324 Indeed,

Rosa (in *Restore*) Dep. Tr. 55:1-4 ("A. ...there are a set of performance characteristics and expectations a surgeon has of any instrument they use.").

Rosa (in *Restore*) Dep. Tr. 49:21-50:4 ("A. ...So this would be things, for example, motion fidelity, so how well is it -- is it moving, sharpness of blades, strength of holding a needle. Q. Alignment? A. Alignment could be another one between the jaws, yes.").

Rosa (in *Restore*) Dep. Tr. 51:1-11 ("A. ...So for alignment of the jaws, if you're asking -- so as the surgeon is using an instrument and they say these jaws are out of alignment, so they'll -- and it's not meeting their needs in surgery or whatever the need may be at the time, grasping of tissue, you know, holding of a needle, whatever that is. The instrument will come out. We expect it to come back to us so that we can analyze it and figure out why the jaws may have gotten out of alignment."); Rosa (in *Restore*) Dep. Tr. 55:4-10 ("A. ...If that instrument is meeting those needs of the particular surgery, they'll move on with it. If it's not, what I -- what I would hope they do is they pull it out, put in another one, and continue the operation so they -- you know, to the -- and keep it up expeditiously for the patient.").

Rosa (in *Restore*) Dep. Tr. 47:3-10 ("A. How do they know that it meets the specifications? Like that -- I mean, if I understand, that's our commitment to the quality and to patient safety. It's what we're supposed to do as a company. During use they may see something that says, hey, this isn't meeting what I expect. And that's when we should see a return.").

Rosa (in *Restore*) Dep. Tr. 48:18-49:8 ("Q. So how does the surgeon know that the instrument is safe to use after that first use? A. I think it -- I think it goes back to we've committed within our testing and with our labeling to a certain number of uses. And that all of our testing internally shows that the -- both the characteristics of use, sharpness, the fidelity of motion, the things the surgeon can see will meet their expectations for surgical performance. And then all of the factors that the surgeon can't *See also* will meet the safety specifications that we've established.").

based on market research surveys conducted by Intuitive, feedback from surgeons generally has been positive on the quality and reliability of the product.³²⁵

143. Surgeon testimony indicates discomfort with using EndoWrist instruments that have had their use counters circumvented. For example, Dr. Francis, who was chief of surgery at Franciscan between 2010 and 2020,³²⁶ and Dr. Maun, another surgeon at Franciscan, stated that they would not use an EndoWrist with a circumvented use counter.³²⁷ Dr. Estape echoed these concerns, stating, "I would want to make sure that we're doing things appropriately and we don't have expired -- anything we use in the operating room."³²⁸ When discussing a meeting he had with another third-party company offering to reset instruments, Dr. Estape described the program as "shady."³²⁹

See, e.g., Intuitive-00578133 at -141 and -155. In a survey of da Vinci Xi users, 82 percent of respondents gave a 9 or a 10 out of 10 in response to the question "how likely are you to recommend the da Vinci Xi system to a colleague?" In addition, 79 percent of respondents rated da Vinci Xi instruments "Much Better" than "other minimally invasive surgical instruments" they use.

Francis (10/14/2022) Dep. Tr. 6:21-23 ("Q. Okay. Am I correct that you were the chief of surgery for Franciscan from 2010 to 2020? A. That's correct.").

Francis (10/14/2022) Dep. Tr. 23:22-25 ("Q. Would you be willing to use an EndoWrist with a circumvented use counter on a patient? ...A. No."). *See also* Maun (11/8/2022) Dep. Tr. 27:7-12 ("Q. Would you be comfortable with using an EndoWrist with a circumvented use counter? A. I probably would not use that. Q. Why not? A. Because then I don't know the history of the number.").

Estape (10/22/2022) Dep. Tr. 60:10-61:1 ("Q. To your knowledge, have you ever used an EndoWrist that has been reset? A. Not to my knowledge. Q. Is that something you would want to know before you performed a surgery? A. Oh, absolutely. Q. Why? A. Well, because these things are cleared only for a certain number of procedures, and so I would want to make sure that we're doing things appropriately and we don't have expired -- anything we use in the operating room, everything that they check, the nurses open, there's an expiration date, there's a usage date, there's all these things. And so if we're doing something off label, I surely want to know about it, and I probably wouldn't participate in it.").

Estape (10/22/2022) Dep. Tr. 57:18-58:7 ("Q. What do you remember about the meeting? A. Well, a company comes in and says that it can wipe out the number of uses on an instrument that's FDA cleared for only ten uses, I thought that was a pretty interesting meeting. Q. Why was it interesting to you? A. Well, you know, everything that we do in medicine is for safety, you know, and certain things are cleared only by the FDA, and it just seemed like a -- for – I'll just use the word shady, a very shady meeting where, you know, oh, I can take this and I

144. Intuitive has demonstrated a long-standing commitment to ensuring that the da Vinci Surgical System is safe and reliable and performs as expected. For example, to this end, Intuitive performed extensive safety testing before setting their initial use count limits and then performed additional testing before increasing the use count limits as part of their Xi extended use instruments. In fact, during its extended use life testing, Intuitive subjected samples of each instrument model to as many as 22 simulated surgical uses (SSU). In every case, a subset of the sample tested to failure before reaching the maximum number of cycles for testing (which ranged from 14 to 22 SSUs). For example, of the 22 long tip forceps tested, 5 tested to failure by the 21st SSU. Based on these results, Intuitive approved this instrument for 18 uses. Evidence shows that the reliability and confidence standards Intuitive uses for a given test case reflect the clinical risks associated with the function being tested. Surgeons rely on this kind of

can wipe off the uses for this instrument and you can keep using it forever. It just didn't seem -- you know, it didn't seem like a very up-and-up program. I've never heard of that before.").

Intuitive-00004692 at -692 ("To analyze the ability of instrument lives to be extended safely, life testing was performed on X/Xi instruments and a cumulative risk analysis was completed and summarized. Life testing that was used previously to validate the specification of 10 lives (for most instruments) was completed 'to failure' to determine the maximum allowable number of lives for each instrument, utilizing knowledge gained from years of instrument usage.").

Intuitive-00552535. Note that in addition to the use lives tested, Intuitive also tested additional reprocessing cycles to account for additional sterilization cycles that occur when an instrument enters the surgical field, but does not end up being used. *See also* Intuitive-00004692 at -699-700 ("Number of uses can be different from the number of reprocessing cycles when an instrument is brought into a sterile field, but is not put on the system and used by the surgeon. The instrument would still need to be reprocessed because it became contaminated by the surgical field, but, since the system-instrument interaction is what deducts the number of instrument lives, the number of uses remaining would remain unchanged. Current reliability testing accounts for these additional reprocessing cycles by testing to 5 additional reprocessing cycles to the Weibull analysis.").

Intuitive-00552535. *See also* Intuitive-00029837 at -840 for definition of "simulated surgical use".

³³³ *Id*.

Intuitive-00004692 at -702 ("Life testing protocols and reports trace to reliability requirements for instruments. The reliability and confidence levels of the life testing test cases vary depending on risk levels associated with different clinical risks and different failure modes."). *See also* Intuitive-00552533; Nixon (10/7/2022) Dep. Tr. 31:23-32:11 ("Q.

safety testing to ensure that the instruments "work as designed" during surgery, 335 and they trust Intuitive to do it. 336

145. Intuitive's commitment to safety is demonstrated by the differences between their pilot instrument refurbishment program (known as "Project Dragon") and the instrument resets facilitated by SIS. Intuitive's assessment of "[Instrument] Refurbishment Feasibility" contemplated that Intuitive would replace significant portions of the instruments (including the

And what's your general understanding of how those use limits were set? A. So for each of the instruments, there is an instrument architecture associated with it. There is a -- control parameters, how the instrument is driven, and a clinical use scenario that goes with each of the instruments, because they complete different surgical tasks. And so the combination of those three things were assessed to determine how we can ensure kind of consistent safety and efficacy of the instrument over the course of the lives of the instrument. And those came together to determine the lifes [sic] that came on the instrument.").

Francis (10/14/2022) Dep. Tr. 23:22-24:15 ("Q. Would you be willing to use an EndoWrist with a circumvented use counter on a patient? ... A. No. ... Q. Why not? A. From what I understand, the number on a repeated use instrument is placed there within a recommendation based on somebody, whether it was the engineers or elsewhere, that stated that was a normal number of uses that would basically give you normal use of the instrument. To go beyond that does not guarantee or in any way imply the instrument will continue to work as designed. And for one, I do not -- I do not like inefficiency. So to have to switch out an instrument that's malfunctioning or not working properly or slowing me down in some way really grates at my performance of operations.").

^{See, e.g., Francis (10/14/2022) Dep. Tr. 24:16-23 ("Q. If Franciscan were to tell you that its hospitals would be stocking EndoWrists that had reset use counters, how would you react? ... A. I -- I would ask specifically if Intuitive had okayed this and what their engineers were saying about it because they're the ones who designed the instrument to begin with."). See also Rosa (in Restore) Dep. Tr. 47:3-7 ("A. How do [surgeons] know that [the EndoWrist instrument] meets the specifications? Like that -- I mean, if I understand, that's our commitment to the quality and to patient safety. It's what we're supposed to do as a company.") and 48:18-49:8 ("Q. So how does the surgeon know that the instrument is safe to use after that first use? A. I think it -- I think it goes back to we've committed within our testing and with our labeling to a certain number of uses. And that all of our testing internally shows that the -- both the characteristics of use, sharpness, the fidelity of motion, the things the surgeon can see will meet their expectations for surgical performance. And then all of the factors that the surgeon can't see also will meet the safety specifications that we've established.").}

cables, inputs and flush tube) to "survive [additional] lives."³³⁷ Rebotix, on the other hand, does not replace any instrument components.³³⁸ In fact, Project Dragon did not launch because, after extensive research and testing into the feasibility of such a program, Intuitive found that the refurbishment program would be "cost prohibitive" relative to manufacturing new EndoWrist instruments.³³⁹

146. Intuitive's methods and the da Vinci Surgical System also have been proven safe and reliable in the field. Since 2012, nearly 6.6 million da Vinci surgeries have been performed in the U.S. by

³³⁷ See Intuitive-00367019 at -052. Intuitive's assessment provided that between 32-72 percent of instrument components would have been "scrap[ped]." (*Id.* at -056.). See also Goodson 30(b)(6) (11/16/2022) Dep. Tr. 40:7-12 ("Q. What is your understanding of refurbishment within the context of Project Dragon? A. Within the context of Project Dragon, refurbishment is the replacement of worn components on an expired Xi instrument to return to like-new performance.") and Nixon (10/17/2022) Dep. Tr. 110:4-14 ("Q. Do you have any understanding as to why [Intuitive did not implement a program to offer remanufactured instruments]? A. It was -- it was deeply assessed to ensure that the instruments would have the same quality performance and safety profile as the original ones that were coming off the line. And in order to do that, there were so many components that needed to be replaced in the device that had potential, you know, wear and tear that the overall cost of deconstructing the instrument and rebuilding it to initial full device was more expensive than the new instrument.").

³³⁸ See REBOTIX162404 (Rebotix EndoWrist Service Procedure). See also Papit (in Rebotix) Dep. Tr. Exhibit 7 at -471.

Morales 30(b)(1) (11/9/2022) Dep. Tr. 172:23-173:20 ("[A.]... I think project Dragon was a program or initiative to explore the feasibility of being able to perform refurbishment on instruments...At the end of the day when this whole thing was said and done, it didn't make sense, and -- and it didn't make sense for a lot of reasons, and the -- the -- the biggest challenge here was the -- all of the logistic work that was required in order to obtain an instrument, bring it back, ensure it was properly sterilized, disassemble, reassemble, repackage, and go through all that. And so, you know, what in- -- what Intuitive was doing, and -- and what other companies were doing were different and, again, at the end of the day, it didn't make sense, it didn't make financial sense, it didn't make, you know, performance sense, and -- and so the project didn't launch."); Goodson 30(b)(1) (10/27/2022) Dep. Tr. 73:9-13 ("A. The requirement for demonstrating the reliability of the instruments repeatedly over life and the cost associated with replacing the parts to achieve that reliability and building a business became cost prohibitive for pursuing the project.") and 74:7-10 ("A. Refurbishment of the Xi instruments to replace components or return it to like new resulted in a cost that would be greater than a new instrument.").

- more than 32,000 surgeons.³⁴⁰ From 2018 to 2021, 4,543 surgeons, performing at least 5 surgeries every quarter, performed over 1.91 million surgeries.³⁴¹
- 147. Evidence indicates that patients often rely on healthcare professionals for information about treatment choice. For example, in a 2018 survey of 420 patients in the U.S. with benign and malignant diagnoses, Intuitive found that 46 percent of patients replied that healthcare professionals are "the most useful source of information," followed by the internet at 25 percent of respondents.³⁴² In addition to the hands-on experience that surgeons, patients, and healthcare providers get through performing or undergoing a da Vinci surgery, Intuitive has invested in developing trust with the medical community. For example, Intuitive has numerous training initiatives and resources for surgeons and care teams to "[support] their safe and effective use of our tools and technologies to help the patients they serve."³⁴³

2. SIS (and third-party companies like it) potentially put patient safety and Intuitive's reputation at risk

- 148. Economic theory predicts that, as a third-party company that did not incur the costs of investments in designing or developing the da Vinci Surgical System and that bears (at most) a fraction of the repercussion of adverse surgical outcomes, SIS does not have the same incentives as Intuitive to protect patient safety and therefore is more likely to put patient safety at risk. That SIS does not have the same incentives to protect Intuitive's reputation and financial viability is indicated by SIS's business practices. For example, as explained below:
 - a. The EndoWrist resets sold by SIS and performed by Rebotix occurred without knowledge of Intuitive's proprietary specifications for the da Vinci Surgical System, including EndoWrist instruments. Hence, not only is SIS unable to ensure that the EndoWrist resets meet the

³⁴⁰ Intuitive-00706097. See Procedures Data Calculation (Section VI.B.2).do.

³⁴¹ *Id*.

³⁴² Intuitive-00122488 ("Summer Internship – Patient Information Journey, Summer 2018") at -504.

³⁴³ Intuitive 2020 Sustainability Report at pp. 13-15.

³⁴⁴ See ¶ 139 above on the principal-agent problem.

- OEM's specifications, SIS does not have access to the complete specification of the system to be able to assess whether the reset would have other ramifications.
- b. Evidence indicates that SIS's representations of its safety testing protocol of the EndoWrist reset process are misleading.
- 149. Both Rebotix, the company that actually performed the EndoWrist reset "service," and SIS, who distributed reset EndoWrist instruments, 345 lack knowledge of Intuitive's proprietary specifications and thus likely lack the means to ensure compliance with those specifications. The deposition testimony of SIS and Rebotix personnel confirm that neither company has Intuitive's product specifications. 346 Mr. Posdal stated that SIS made no attempts to confirm Rebotix's claims about the EndoWrist reset process, and rebranded Rebotix marketing materials claiming that reset EndoWrists had been "repaired to original specifications." Without Intuitive's specifications, neither Rebotix nor SIS was in a position to claim that the reset EndoWrist instruments met the OEM's specifications, which have been cleared by the FDA.
- 150. In addition, evidence reflects that SIS's representations of safety testing are misleading and inadequate. Mr. Posdal asserted that EndoWrist instruments could be reset "significantly more

 $^{^{345}}$ See ¶¶ 47-48 above.

Posdal 30(b)(6) (11/1/2022) Dep. Tr. 57:12-57:19 ("Q. Mr. Posdal, I had one follow-up question that pertains to Topics 1 and 4. Has SIS ever had access to the -- to Intuitive's original specifications for EndoWrist instruments? A. No. Q. And has SIS ever had access to Intuitive's design history files for EndoWrist instruments? A. No."). See also Papit (in Rebotix) Dep. Tr. 167:14-21 ("Q. Did Rebotix market to potential customers that it would repair the EndoWrist to their original function and specifications? A. That sounds fairly accurate. Q. Did Rebotix have access to the OEM specifications for EndoWrists? A. Intuitive doesn't publish their specifications."); Hamilton (in Rebotix) Dep. Tr. 110:18-21 ("Q. ... Do you agree that at no time did Rebotix or Rebotix Panama have a complete set of the factory specifications for the EndoWrist instruments? A. Yes."); DeSantis (in Rebotix) Dep. Tr. 244:5-11 ("A. ...our specifications and our requirements are our intellectual property of the company which we've not released. So I don't know how a third party would be able to ensure and guarantee that their quality system – that they were developing to our specs, that their quality system was sufficient and on part with us, et cetera, et cetera.").

³⁴⁷ Posdal 30(b)(6) (11/1/2022) Dep. Tr. 65:15-67:23 and Exhibit 136 at p. 10.

than ten" times.³⁴⁸ When asked if SIS believes it is safe to use an EndoWrist 19 times, he responded that it would, though he acknowledged that this belief is not based on experience specific to EndoWrists.³⁴⁹ In fact, SIS did not perform any independent testing before marketing its reset program and instead relied on Rebotix's testing of the reset process.³⁵⁰ The deficiency in testing for patient safety further demonstrates that SIS does not hold patient safety to the same rigorous standard as that which is set by Intuitive for the da Vinci Surgical System.

151. When the increase in risk to patient safety is accounted for, SIS's purported cost savings are much lower than it markets to Intuitive's customers. As an example, I focus on the ProGrasp

Posdal 30(b)(6) (11/1/2022) Dep. Tr. 36:22-37:9 ("Q. Sure. How many surgical uses is it safe to use an EndoWrist for before the EndoWrist goes through the reset process that SIS has marketed? ...[A.] I can only say that it depends. Much like the instruments that we repair every day, it depends on how that instrument was handled or treated. The limitation on EndoWrist specifically render that point moot after ten uses. So if you're asking me how long and how many times it can be reprocessed, that would depend, but it would be significantly more than ten.").

Posdal 30(b)(6) (11/1/2022) Dep. Tr. 41:4-20 ("Q. Does S -- does SIS believe that an EndoWrist is safe to be used 19 times? A. Yes. Q. And what is that belief based on? A. 50 years of repairing medical equipment that is substantially equivalent. Q. So nothing specific to the EndoWrist instruments themselves; correct? A. Can you repeat that or rephrase that. Q. Sure. SIS's belief that EndoWrist is safe to be used 19 times is not specific to any testing or validation that SIS has done on the EndoWrist instruments; correct? ...[A.] I guess that would be correct.").

Posdal 30(b)(6) (11/1/2022) Dep. Tr. 22:23-24:1 ("Q. I'll focus first on the reset program. Did SIS perform any testing of its own regarding the reset program before SIS first marketed it? A. No. We were in a partnership with Rebotix for a number of -- Benjamin Biomedical and Rebotix, they do some repairs and some components for us, harmonic scalpels and Phaco handpieces and video cameras, which are considerably more complex in the EndoWrist we're speaking about, and they have -- they had done a great job of those over the number of years. We saw their test results and -- and as I had mentioned prior, the visit to Rebotix where we walked through the process, and we were satisfied that the testing they'd done -- they had done was adequate, especially with regard to our expertise in -- in regular instrument device repair for the last 50 years. The only thing that's really different about this process is the chip counter itself. Q. Okay. So I -- I understand that SIS may have had a partnership with Rebotix. But my question was -- was focused solely on testing that SIS did itself. And I'm -- I'm correct in understanding that SIS did not perform any of its own testing for the reset process; correct? A. That is correct.").

Forceps EndoWrist instrument, which comprised 11.7 percent of SIS's EndoWrist reset sales.³⁵¹ On a per use basis, a new ProGrasp Forceps from Intuitive would be \$220 whereas a reset instrument from SIS would be \$130.³⁵² The healthcare provider "saves" \$90 per use with SIS's reset instrument over Intuitive's new instrument. Internal testing by Intuitive demonstrates that EndoWrist instruments have a limited number of reliable uses.³⁵³ Furthermore, I understand that gradual degradation over time is one of the risks identified through Intuitive's risk analyses and life testing, which is factored into the established use limits.³⁵⁴ Hence, evidence indicates that the healthcare provider effectively trades off \$90 in "savings" for an increase in the probability of instrument failure. SIS's "savings" potentially come at the cost of a safe and successful da Vinci

³⁵¹ Smith Counterclaims Damages Report at Table 1. 0.117 = \$6,500 in [C][4] / \$55,700 in [C][15].

REBOTIX001387 at -394 and SIS010647. This calculation does not account for the fact that, for its initial EndoWrist reset with SIS, the customer needs to send the EndoWrist with one remaining use. See Posdal 30(b)(6) (11/1/2022) Dep. Tr. 40:6–10 ("Q. So the -- the first time that SIS facilitates a -- a reset, the instrument needs to have at least one use remaining on it; is that right? A. That is correct.").

DeSantis (in *Rebotix*) Dep. Tr. 132:14-24 ("Q. Well, when you're submitting documentation about an EndoWrist to the FDA, you include a proposed number of lives for that instrument; right? A. Yes. Q. And then some documentation that supports that number of lives for the instrument; right? A. Yes. We -- we provide them with the specifications for the instrument, including number of lives. And then we have to prove that we're sure it will work for those number of lives, and -- and they ask for that data."); DeSantis (in *Rebotix*) Dep. Tr. 169:6-17 ("A. ...The life -- the life rating was based on whatever we can get out of [the extended life instruments]. We tested them, you know, to the point where we can statistically indicate them. That's why we ended up with, in my opinion, a sub-optimal stratification: Sum 12, sum 14, sum 18. It was the most we can get out of them at our statistical testing for our specifications and requirements. That has nothing to do with the financials. It was after we determined the number of lives that we can confidently statistically claim, then how do we price them.").

I understand that Dr. Howe has concluded that gradual degradation of an instrument was one of the risks identified by Intuitive and factored into Intuitive's risk analyses and life testing. I also understand that Dr. Howe opined that he would expect SIS's reset efforts (which were actually performed by Rebotix)—and the use of EndoWrist instruments beyond the limits prescribed by Intuitive—would increase instrument failure rates due to increased wear and tear. *See generally* Howe Report § V; *see also id.* at ¶ 108 (explaining the correlation between increased instrument use and instrument problems demonstrated in Rebotix's own analyses).

surgery to the patient, which is an expected cost that I have not seen SIS consider or communicate to customers or patients.

- 152. Intuitive's conduct—particularly in light of third-party resets of Si EndoWrist instruments—has been consistent with a manufacturer concerned with patient safety as opposed to a monopolist. For example, in 2020, Intuitive rolled out its Extended Use Program in which it increased use limits by varying amounts for 13 Xi EndoWrist instruments, and the cost per use for these instruments decreased, rather than increased. The decay evidence indicates that competition with traditional laparoscopy, including for benign procedures in the U.S., was a key objective of Intuitive's Extended Use Program. Evidence also shows that the variation in use limits, which ranges from 12 to 18 uses, is based on extensive testing by Intuitive. This conduct is more consistent with a company that continues to try to find ways to compete in spaces historically occupied by other surgical modalities—e.g., traditional laparoscopy—as opposed to a company that is trying to extract monopoly rents.
 - 3. Intuitive's reputation and future would be at risk if SIS and others were allowed to reset EndoWrist instruments

Intuitive-00560028 at -034 and -038. *See also* Intuitive Surgical, Da Vinci X/Xi Instrument & Accessory Catalog October 2021, accessed January 6, 2023, https://www.intuitive.com/en-us/-/media/ISI/Intuitive/Pdf/xi-x-ina-catalog-no-pricing-us-1052082.pdf. *See also* Intuitive-00004692 at -692.

Intuitive-00840257 at -069 ("Objective: Leverage the economic benefit of Extended life instruments to lower the barrier to adoption with a focus on targeted cost sensitive procedures."), -278 ("Intuitive's product offering is increasingly aligned with economic realities of my hospital, and allowing me to offer da Vinci as a first choice to a broader set of patients than before...Standardize instruments used in targeted procedures: benign surgery in U.S., malignant surgery in EU to bring per procedure costs closer to lap."), and -286 (comparison of Current I&A, Lap I&A, and Proposed I&A costs for cholecystectomy, inguinal hernia repair, and benign hysterectomy for the U.S.).

³⁵⁷ See ¶ 144 above. In addition, Intuitive made changes to the design of the instrument to ensure that the extended use instrument would perform at Intuitive's quality standards; see fn. 387 below.

- 153. As discussed above, third-party companies (such as SIS) do not have the same incentives as Intuitive to protect patient safety and the reputation of the da Vinci Surgical System.³⁵⁸ This is reflected in the evidence showing the inadequacy of SIS's testing and knowledge about the components of the da Vinci Surgical System and the system as a whole discussed above. Risk to patient safety not only endangers the health of the patient, but also poses significant risk to Intuitive's reputation and future business.³⁵⁹
- 154. There are numerous ways in which adverse events to patients can harm Intuitive's reputation and future business. One way is that the FDA publicizes adverse events associated with medical devices in its MAUDE database, which is publicly accessible. Another way is that adverse events, or the risk of adverse events, may lead to news or "safety communications" that could impact whether healthcare professionals recommend da Vinci surgery as a treatment option. For example, the FDA issued a "[s]afety [c]ommunication" on August 20, 2021 to warn patients and healthcare providers that the "safety and effectiveness of using robotically-assisted surgical (RAS) devices for use in mastectomy procedures or in the prevention or treatment of cancer ha[s] not been established" nor has the FDA "evaluated the safety or effectiveness of RAS devices for the prevention or treatment of cancer, based on cancer-related outcomes." This "high-profile publication and an FDA warning" may have deterred some surgeons from MIS

³⁵⁸ See ¶ 139 and \S VII.B.2 above.

Intuitive 2021 Form 10-K at p. 27 ("Our success depends on the quality and reliability of our products... Because our products are designed to be used to perform complex surgical procedures, due to the serious and costly consequences of product failure, we and our customers have an increased sensitivity to such defects.").

³⁶⁰ See fn. 317 above.

[&]quot;Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication," U.S. Food & Drug Administration, February 28, 2019, accessed January 6, 2023, https://www.fda.gov/medical-devices/safety-communications/update-caution-robotically-assisted-surgical-devices-mastectomy-fda-safety-communication.

radical hysterectomy in favor of open surgery.³⁶² These examples show how risks to patient safety can have significant consequences for Intuitive's business.

155. Evidence indicates that within a short period of time after identifying third-party resets, Intuitive usually expresses its concern that these resets can impact the safety of patients and the effectiveness to the system. Indeed, I understand that Dr. Howe identified "at least 19 additional instrument failures following the extension of an EndoWrist's useful lives by Rebotix's installation of the Interceptor."

C. INTUITIVE'S SALE OF INTEGRATED SYSTEMS HAS FOSTERED PROCOMPETITIVE INNOVATIONS AND QUALITY IMPROVEMENTS

156. Intuitive continuously has innovated on the da Vinci Surgical System, including the da Vinci platform and instruments. Since 1998, the company has released four generations of da Vinci platforms.³⁶⁵ Intuitive offers the "largest library of end effectors" among robotic-assisted surgical

³⁶² Krishnansu S. Tewari, "Minimally Invasive Surgery for Early-Stage Cervical Carcinoma: Interpreting the Laparoscopic Approach to Cervical Cancer Trial Results," *Journal of Clinical Oncology* 37, no. 33 (2019): 3079.

For example, approximately a month after Conway Regional Medical Center ("Conway") first used a reset EndoWrist instrument, Intuitive sent a letter to Conway's operating room director that stated: "Continued use beyond this determined useful life, normal wear and tear may impact instrument performance. ... Any of this degraded product performance could impact the procedure and result in unintended safety risks to the patient." *See* Intuitive-00288971 (on the timeline) and Intuitive-00288975 (Intuitive's letter to Conway).

Howe Report, ¶ 77. See also Howe Report, ¶¶ 75-76 for descriptions about types of failures after instruments had their "useful lives extended by third parties, such as Restore and Rebotix," and customer complaints.

 $^{^{365}}$ See ¶ 29 above.

One example of an improvement from the third generation (Si) to fourth generation (Xi/X) is that the da Vinci Xi patient cart has a "gantry system to position the instrument manipulators directly overhead the operating table." In contrast, the "reachable workspace" of the da Vinci Si patient cart is "highly dependent on the orientation of the cart." See Azizian et al. at p. 10.

systems.³⁶⁶ A customer survey conducted by Intuitive in 2017 indicates that customers consider Intuitive to be innovative and high quality.³⁶⁷

- 157. Integration of Intuitive's surgical system (or "bundling" the components of the da Vinci Surgical System) encourages Intuitive to pursue these innovations. There are several ways in which offering an integrated product, or bundling, preserves a company's incentives to continue innovating. First, as explained above, selling an integrated system mitigates risks to Intuitive's reputation, which could pose significant risk to the financial viability of an investment. The Second, bundling can help to ensure that components are compatible across the system and reduce costs associated with coordination across separate companies. Third, bundling can reduce the risk that third parties will take advantage of Intuitive's IP without sharing in the cost (and entailed risk) of development. The As I next explain further, each of these factors likely influences Intuitive's decision to offer the da Vinci Surgical System as an integrated product.
- 158. First, allowing a third party such as SIS to reset EndoWrist instruments not only poses significant risks to the patient safety, reputation, and financial viability associated with Intuitive's existing

Longmore et al. at p. 13. As examples of the introduction of new instruments, Intuitive obtained FDA clearance for its EndoWrist One Vessel Sealer in December 2011 and its EndoWrist Stapler 45 Instrument with Blue and Green 45 mm reloads in October 2012. See Intuitive 2014 Form 10-K at p. 7.

Intuitive-00143279 ("2017 Global Customer Satisfaction Survey: United States") at -284 (sixty-three percent of customers responded that they expected Intuitive Surgical to be "in a STRONGER position in five years," and the top volunteered reasons included: (i) innovation (64 percent); (ii) quality of products (42 percent); (iii) track record (42 percent), and (iv) training/education (42 percent)). See also -293 (80 percent of respondents felt that Intuitive "has a strong track record of developing robotic-assisted surgical programs for hospitals" while 84 percent felt that Intuitive "offers high-quality products").

³⁶⁸ As discussed in Section IV.F above, the riskiness of an investment influences the decision of whether to invest in the first place.

See ¶ 137.b above. Professor Tirole's arguments on tying would similarly apply to "bundling" in the context of the da Vinci Surgical System. As I understand, both the da Vinci platform and EndoWrist instruments are integral to the functioning of the system, and there is little distinction between tying and bundling when one good is "valueless" without the other (see Section III.B and fn. 309 above).

 $^{^{370}}$ See ¶ 137.d above.

surgical systems, it also may dampen Intuitive's incentives to continue investing in improvements to the da Vinci family of surgical systems.³⁷¹ That is, as a matter of basic economics, Intuitive's incentives to invest in new generations of da Vinci Surgical Systems depends on the returns it expects to make on those investments. And, to the extent that bad patient outcomes harm Intuitive's reputation with potential customers, current and/or expected future resets by third parties that increase the risk of bad patient outcomes may decrease Intuitive's expected returns on investments and thus dampen its incentives to invest.

- 159. Second, as previously discussed,³⁷² the da Vinci Surgical System was designed based on four "product pillars" that depend on various components of the system working together.³⁷³ Compatibility of the technology is critical to the function of the da Vinci Surgical System. Many of the parts for the system are "specially designed for Intuitive," including parts for the da Vinci platform and the EndoWrist instruments.³⁷⁴ Unbundling the parts would be potentially costly to Intuitive, which would need to incur costs to accommodate parts that were not designed as part of system, and possibly to the healthcare provider, which would have to source the correct components.³⁷⁵ The integrated system saves on these compatibility costs for Intuitive, increasing its incentives to invest in the development of the system.
- 160. Third, potential for a third party to take advantage of Intuitive's IP without sharing in the costs (and entailed risks) of development is another concern that may arise with an unbundled product. The third party is effectively "free riding" on the innovator's (here, Intuitive's) IP. 376 A "free

As I described in fn. 319 above, healthcare providers likely also do not fully internalize the potential ramifications of their actions on Intuitive's reputation and financial viability.

 $^{^{372}}$ *See* ¶ 60 above.

³⁷³ *See* ¶ 61 above.

Rosa (in *Restore*) Dep. Tr. 15:23-19:17 (on the da Vinci Si platform) and 20:16-22:2 (on the da Vinci Xi platform); DeSantis (in *Rebotix*) Dep. Tr. 23:8-24:4 (on instruments, including EndoWrists). *See also* Robinson (in *Restore*) Dep. Tr. 14:18-22.

 $^{^{375}}$ *See* ¶ 137 above.

A third party can also "free ride" on a company's reputation or brand. For example, in an SIS slide deck titled "da Vinci EndoWrist Repair Process," SIS claims that the "serviced device"

rider" is defined as a "[c]onsumer or producer who does not pay for a nonexclusive good in the expectation that others will."³⁷⁷ Free riding is recognized in economics as one of the reasons for the under-provision of certain types of goods, which may include new ideas in the absence of IP protection.³⁷⁸ Intuitive's "closed" system increases its ability to protect its IP, increasing its incentives to continue investing in new innovations.

opportunism in the form of "free riding." SIS benefits from the IP underlying the da Vinci Surgical System without paying for the investment costs.³⁷⁹ The fact that SIS's prices are set as a percentage of Intuitive's list prices, as opposed to SIS's (or Rebotix's) own costs, is indicative that SIS is free-riding on Intuitive's innovations. SIS's list prices for reset EndoWrist instruments range from 52.0 percent to 78.6 percent of the price of a new EndoWrist from Intuitive (i.e., a

will function identically to a new OEM EndoWrist." SIS091199 at slide 2. *See also* SIS001684.

³⁷⁷ Pindyck and Rubinfeld at p. 693.

The concept of "free riding" is also captured in the testimony of Rebotix personnel; *see* Papit (in *Rebotix*) Dep. Tr. 134:5-135:3 ("Q. Has Rebotix ever identified any of its business partners attempting to reverse engineer the Interceptor? A. I have no knowledge of any attempts. Q. Is that something that Rebotix would allow its business partners to do? A. No. Q. Why not? A. Because it's our process that we patented, and it's our repair product. Q. Any other reasons why? A. Why would we just give that away? It just doesn't make any sense. Q. Rebotix invested a lot of money into developing that technology, right? A. That – that's part of the correct answer. ...Q. What's the rest of the correct answer? A. A lot of time and a lot of openings created in the marketplace by us.").

³⁷⁸ Id. Specifically, free riding can lead to the under-provision of public goods, which are goods for which "marginal cost of provision to an additional consumer is zero and people cannot be excluded from consuming it" (Pindyck and Rubinfeld at p. 690). New ideas without IP protection may constitute a public good since ideas can be shared across many people at no additional cost.

Even with protection, IP litigation can be costly to the innovator (in financial terms and with respect to time), and the use of the IP by the third party may have already cause irreparable harm. Thus, the innovator has an incentive to deter "free riding" before it happens.

Similarly, a healthcare provider that breaches the SLSA with Intuitive and seeks a third party reset of the EndoWrist instrument is "free riding" on Intuitive's innovations. The pecuniary "savings" that the healthcare provider achieves are taken at Intuitive's expense, although the healthcare provider did not share in the costs of investing in the technology.

- 21.4 percent to 48.0 percent discount). At these "discounted prices," SIS still would earn—according to Mr. Bero—gross margins of 27.3 to 28.5 percent and incremental profit margins of 14.3 to 15.4 percent as a distributor of reset S/Si EndoWrist instruments without any ownership of the "technology" or production process. 381
- 162. With its integrated surgical system, Intuitive has continued to invest at a level that is consistent with the protections afforded to them by the challenged conduct, as predicted by economic theory. Intuitive's reported annual R&D expenditures have grown from \$11.1 million in 1999 to \$671.0 million in 2021. ³⁸² As a share of revenue, annual R&D expenditures increased from 7-9 percent between 2005 and 2016 to 12 percent in 2021. ³⁸³ Intuitive's R&D expenditures have contributed to the innovative products highlighted above ³⁸⁴ and enabled Intuitive to maintain its public perception as an innovative company in the industry. ³⁸⁵
- 163. Intuitive likely would reduce its investments in innovation if the protections provided by the challenged conduct were not allowed. Companies may rationally decline to invest in an innovative project if the expected return is below the estimated costs.³⁸⁶ Indeed, Intuitive evaluates the costs and expected benefits of new product development in deciding how to

³⁸⁰ See SIS Pricing Workpaper.

³⁸¹ "Bero Natives.xlsx," tab "3.1." Gross margins are calculated as: (Average selling price in row 11 – Repair costs (including chip costs) in row 14) / Average selling price in row 11. Incremental profit margins are calculated as: Lost profits per unit in row 19 / Average selling price in row 11.

³⁸² Intuitive 2021 10-K at, p. 84. *See also* Public Data Workpaper.

See Public Data Workpaper, which includes a comparison of Intuitive's share to those of publicly traded companies that it named in its 2019-2021 Form 10-Ks and companies named in IBISWorld's 2020 report on "Robotic Surgery Equipment Manufacturing." Intuitive's R&D as a share of revenue is in line with the other companies and, after 2014, is higher than that of companies such as Medtronic.

 $^{^{384}}$ See ¶¶ 69, 156 above.

³⁸⁵ *See* fn. 367 above.

³⁸⁶ See, e.g. Jonathan Berk and Peter DeMarzo, Corporate Finance, Fourth Edition (Essex: Pearson Education Limited, 2017), 101.

allocate the company's resources.³⁸⁷ Therefore, compelling Intuitive to change how it chooses to sell its product (as an integrated system) could have adverse consequences on innovation.

D. INTUITIVE IS ABLE TO OFFER CUSTOMERS A SUPERIOR FINANCIAL DEAL WITH AN INTEGRATED PRODUCT

- 164. As discussed above, customers benefit from Intuitive's integrated system (or "bundle") because the integrated system protects patient safety and preserves incentives to innovate. In addition, customers likely benefit from lower overall costs and greater access to the da Vinci Surgical System with Intuitive's "bundle" than with separate components. I first summarize the economics of bundling of complements and cost savings, both to the customer and to the manufacturer. Then, I discuss how Intuitive's pricing strategy likely is efficient and financially beneficial to customers.
- 165. Academic research has shown that the bundling of goods, including complementary goods, can lead to lower prices for customers. See Complementary goods (or simply "complements") are goods for which an increase in the price for one good decreases the demand for the other goods. See For example, automobiles and gasoline are complements where higher automobile prices will reduce the number of automobile purchases or leases as well as overall consumption

See, e.g., Intuitive-00601505 ("Product Portfolio Guidelines") on funding of R&D programs and Intuitive-00293400 ("da Vinci SP, Business Review III," April 2017) on the business plan prior to the launch of the da Vinci SP in 2018; and Intuitive-01172898 (cover email), Intuitive-01172899 ("Long-term opportunity portfolio assessment") and Intuitive-01172908 ("Opportunity portfolio assessment_v50.xlsx") on analyzing long-term opportunities.

See, e.g., Bruce Kobayashi, "Does Economics Provide a Reliable Guide to Regulating Commodity Bundling by Firms? A Survey of the Economic Literature," Journal of Competition Law and Economics 1, No. 4 (2005): 707-746 for a survey of the economics literature on bundling through the time when the article published. Discussions of lower prices for bundles of products, including complementary products, can be found at, for example, pp. 708-710, 714, and 738-739. See also Hooman Estelami, "Consumer Savings in Complementary Product Bundles," Journal of Marketing Theory and Practice 7, No. 3 (1999): 107-14.

³⁸⁹ Pindyck and Rubinfeld at p. 24.

of gasoline because there are fewer cars on the road. Conversely, lowering the price for a good will increase demand for goods that are its complements.

- 166. Economic principles lead to the prediction that the price of a bundle of complementary goods is lower than the sum of the prices when the goods are sold separately by two different suppliers. 390 The reason is that the supplier that sells the bundle internalizes the "spillover" in demand from one good to its complement(s). In other words, the supplier is willing to offer a lower price on a good when it is able to realize the additional sales of the complementary goods. Customers benefit from lower prices, and the supplier achieves higher profits. 391 This win-win situation makes bundles of complements attractive to both customers and suppliers and, understandably, is common in retail (e.g., right shoes and left shoes, vacation packages). 392
- 167. By selling an integrated system or "bundle," Intuitive is able to efficiently respond to competitive conditions and customer needs as exemplified by its pricing discounts or concessions and leasing arrangements:
 - a. Intuitive can offer discounts and pricing concessions on the da Vinci platform, service, or instruments and accessories.³⁹³ Discounts aim to "[remove] a barrier for customers to expand

Jay Pil Choi, "Mergers with Bundling in Complementary Markets," *Journal of Industrial Economics* 56, No. 3 (2008): 555 (Choi shows that, in the short-run, a merged firm will "reduce the price of its bundled system and expand market share relative to the situation prior to the merger. Prior to the merger, any price cut by one of the merging firms would tend to benefit the other's sales. ...Following the merger, however, the merged entity can 'internalize' these 'pricing externalities' arising from the complementarity of their components by reducing the price of the bundle to below the level the two players would choose if acting independently.").

³⁹¹ Suppliers may also benefit from lower costs of selling a bundle rather than individual goods; *see* David S. Evans and Michael A. Salinger, "The Role of Cost in Determining When Firms Offer Bundles," *The Journal of Industrial Economics* 56, No. 1 (2008): 144-45.

Pindyck and Rubinfeld at p. 426 (vacation package example); David S. Evans and Michael Salinger, "Why Do Firms Bundle and Tie? Evidence from Competitive Markets and Implications for Tying Law," *Yale Journal on Regulation* 22, 37 (2005): 40-41 (on examples of tying in competitive markets).

Intuitive-00372053 ("DiscountingPrinciples_v2.docx"); Intuitive-00021011.xlsx ("Concessoin [sic] Planning OVerview [sic] w BU + Sales Input.xlsx").

their business with [Intuitive]," and Intuitive prioritizes discounts on the da Vinci platform before discounts on system servicing and on instruments and accessories.³⁹⁴ For example, in a pricing negotiation with Benefis Health System, Intuitive offered a discount on the da Vinci platform (that was on par with discounts with other customers) and accommodated Benefis' request regarding its service contract, but it did not offer discounts or differential pricing on instruments ("disposables") because of the company's "strong one-price policy" related to instruments and accessories.³⁹⁵

- b. Intuitive has developed alternative pricing arrangements in which the company shares financial risk with the customer. ³⁹⁶ For example, Intuitive offers various leasing arrangements with customers, including operating leases (which are a "straight-line" payment over the lease term) and usage-based arrangements (which are payments made "as the systems are used"). ³⁹⁷ These arrangements offer "customers with flexibility regarding how they acquire or obtain access to [Intuitive's] systems." ³⁹⁸
- 168. If Intuitive was unable to sell an integrated system and thereby deter third parties from intervening with (and adulterating) system components, then the overall price of the system likely would increase or the quality of the product—measured by patient safety and clinical outcomes or by innovation—would suffer. If Intuitive were not free to protect the safety and welfare of patients, and by extension Intuitive's reputation and financial viability, through

³⁹⁴ Intuitive-00372053 at -053.

³⁹⁵ Intuitive-00203904 at -905.

The sale of instruments on a per-use basis is also a form of risk sharing between Intuitive and its customer. Before acquiring a da Vinci platform, the customer faces some uncertainty about its volume of da Vinci surgeries. Because instrument sales are proportional to the customer's volume of procedures and costs are incurred over time, a portion of the overall cost of the da Vinci Surgical System is therefore spread out and varies with the customer's realized volume.

Intuitive 2019 Form 10-K at pp. 47-48. Between 2018 and 2019, Intuitive reported that the share of da Vinci Surgical Systems that were shipped as leases increased from 25 percent to 34 percent (Intuitive 2019 Form 10-K at p. 57). An example of a usage-based arrangement is AMP, or "accelerating minimally invasive program." *See* Rosa (in *Restore*) Dep. Tr. 25:13-15 and 27:15-32:3 (on AMP).

³⁹⁸ Intuitive 2019 Form 10-K at p. 47.

contractual provisions, the economically rational response could be to change its pricing strategy to achieve as much system integration as possible (e.g., perhaps by increasing its prices for da Vinci platforms and lowering its prices for EndoWrist instruments). Standard economic principles would dictate that Intuitive's re-optimization under such a constraint on its contracting practices likely would harm consumers. ³⁹⁹ One potential consequence is reduced access to the da Vinci Surgical System for some healthcare providers as well as patients who would otherwise have da Vinci surgeries as a treatment option. Alternatively, as discussed above, the quality of the da Vinci Surgical System may decrease if Intuitive is unable to maintain its tight control over patient safety or if Intuitive does not expect to realize returns on its innovative endeavors that would justify the investment costs. ⁴⁰⁰ In all of these circumstances, Intuitive's direct customers (healthcare providers) as well as surgeons and patients likely would be worse off when Intuitive cannot sell its surgical system as it designed, created, and commercialized.

Loren K. Smith, Ph.D. January 18, 2023

See, e.g., Tirole at p. 16 ("A well-known rationale for tying is that a tie enables the metering of demand and prices to depend on consumer usage. ... suppose that some consumers use M on a stand-alone basis while others use M in combination with C or C'. Under unbundling, the producer of M is forced to charge a single price for M, even though the two groups' willingness to pay may be quite distinct. For example, if consumers without demand for the complementary product have a low willingness to pay for M, the producer of M may end up charging a high price for M and prevent them from consuming. By contrast, a tie enables the producer of M to charge a low price for the basic good and a high price for the combination, which avoids excluding the first group and raises economic efficiency.").

In a draft business plan dated October 29, 1995, Intuitive contemplated that "systems will be placed for little or no charge at sites that sign an annual minimum disposables and [Reposable Transmission Unit] purchase contract" (Intuitive-00595673 at -682-683).

⁴⁰⁰ See ¶¶ 153-155, 163 above.

APPENDIX A. DATA PREPARATION AND SUPPLEMENTAL ANALYSES

1. This appendix describes the data sources used in preparing the substitution and pricing analyses in my Report. It also provides supplemental analyses related to substitution and pricing.

A. DATA SOURCES FOR SUBSTITUTION AND PRICING ANALYSES

1. Intuitive's System Sales Transactions Data

- 2. I use data provided by Intuitive covering its worldwide da Vinci platform transactions from January 2012 through December 2021. Below, I list the fields relevant for my analysis as well as my understanding of these fields:²
 - Period Qtr: year and quarter of transaction
 - Company Code: selling legal entity
 - Country: country of transaction
 - Lease Type Description: description of lease if transaction is a lease
 - Transaction Category: category of transaction

 ²⁰¹²⁻²⁰¹³ System Transactional Data - Intuitive-00695237, 13Q3 - Intuitive-00595463, 13Q4 - Intuitive-00595462, 14Q1 - Intuitive-00595458, 14Q2 - Intuitive-00595459, 14Q3 - Intuitive-00595460, 14Q4 - Intuitive-00595461, 15Q1 - Intuitive-00595454, 15Q2 - Intuitive-00595455, 15Q3 - Intuitive-00595456, 15Q4 - Intuitive-00595457, 16Q1 - Intuitive-00595450, 16Q2 - Intuitive-00595451, 16Q3 - Intuitive-00595452, 16Q4 - Intuitive-00595453, 17Q1 - Intuitive-00595446, 17Q2 - Intuitive-00595447, 17Q3 - Intuitive-00595448, 17Q4 - Intuitive-00595449, 18Q1 - Intuitive-00595442, 18Q2 - Intuitive-00595443, 18Q3 - Intuitive-00595444, 18Q4 - Intuitive-00595445, 19Q1 - Intuitive-00595441, 19Q2 - Intuitive-00595440, 19Q3 - Intuitive-00595439, 19Q4 - Intuitive-00595431, 20Q4 - Intuitive-00595430, 21Q1 - Intuitive-00595429, Intuitive-00849019.xlsx.

For a discussion of the Systems data fields *see* Intuitive Surgical, Inc. Responses to Restore's Data Questions, July 10, 2021, at pp.1-4; Intuitive Surgical, Inc. Responses to Class Plaintiffs' Data Questions, at pp. 2-6; Intuitive Surgical, Inc. Intuitive's Responses to Class Plaintiffs' Second Follow-Up Data Questions, at pp. 1-2.

- Trade In System Type: type of system if transaction is a trade in
- No of Trade In Systems: number of trade in systems if transaction is a trade in
- System Name: name of system
- System Type: type of system (e.g. "System", "Simulator", "Loaner", "Upgrade", etc.)
- Total System Revenue (USD): total system revenue in USD
- Total System Qty: total system quantity

2. Intuitive's Instruments & Accessories Sales Transactions Data

- 3. I use data produced by Intuitive that cover all worldwide sales for instruments and accessories ("I&A") from January 2012 through December 2021.³ Below, I list the main fields as well as my understanding of them:
 - Posting Date: date of data referenced⁴
 - Comp Code: selling legal entity⁵
 - Customer: "Code identifying [a] specific customer"
 - Customer Name: text field corresponding to the customer code⁷

Intuitive-00695234, Intuitive-00695144, Intuitive-00595436, Intuitive-00595435, Intuitive-00595434, Intuitive-00595406, Intuitive-00595407, Intuitive-00595408, Intuitive-00595409, Intuitive-00595410, Intuitive-00595411, Intuitive-00595412, Intuitive-00595413, Intuitive-00695233, Intuitive-00595415, Intuitive-00595416, Intuitive-00595417, Intuitive-00595418, Intuitive-00595419, Intuitive-00595420, Intuitive-00595421, Intuitive-00595422, Intuitive-00595423, Intuitive-00595424, Intuitive-00595425, Intuitive-00595426, Intuitive-00595427, Intuitive-00695232, Intuitive-00595428, Intuitive-00701322, Intuitive-00706090; Intuitive Surgical, Inc. Responses to Rebotix Repair, LLC's Data Questions, July 10, 2021.

Intuitive Surgical, Inc. Responses to Rebotix Repair, LLC's Data Questions, July 10, 2021, at p. 2.

⁵ *Id*.

⁶ *Id*.

⁷ *Id*.

- Ship-to Party: "Code identifying shipping information"⁸
- Ship-to Party Name: "Customer name or identifying code" 9
- Product: "Code identifying the product sold" 10
- Material Description: text field that "identifies the item sold," le.g., "STAPLER, SUREFORM 60, SPU, BOX OF 6, IS4000"
- Sales Qty: quantity sold 12
- Unit: values include "BOX," "EA," "FT," "ROL," and "USE" 13
- Currency: currency in which customer paid¹⁴
- Net Sales: "Total net sales, subtracting discounts from gross sales" 15
- 4. Net Price per Qty: "Net sales by currency divided by the quantity of product sold (i.e., the value in the field 'Net Sales by Curr' divided by the value in the field 'Sales Qty')" Sales records with negative values can represent returns, credits, or other adjustments such as rebates. Sales records with Sales Qty equal to zero pertain to "adjustments separate from a sale, such as rebates or contractual credit memos."

⁸ *Id*.

⁹ *Id*.

¹⁰ *Id*.

¹¹ *Id*.

¹² *Id*.

¹³ *Id*.

¹⁴ *Id.* at p. 3.

¹⁵ *Id*.

¹⁶ *Id*.

¹⁷ *Id.* at p. 4.

¹⁸ *Id*.

- 5. I incorporate additional descriptive information for each instrument into the I&A transaction data using the "product map" file produced by Intuitive. ¹⁹ This file includes the following main fields:
 - Material Num: "Code identifying the product sold"²⁰
 - Base Material: "Code identifying type of product"²¹
 - Material Name: "Name of specific product"²²
 - Product Platform: "Identifies which da Vinci model is used" 23
 - Base UOM: "Base unit of measure, (e.g., box, each, or number of uses)"²⁴
 - Number Of Uses (if Each) or Qty per Box (if Box): "Number of uses for product serviced if reusable or number of boxes of the product that is sold" 25

3. Intuitive's da Vinci Procedures Data

- 6. I utilize Intuitive's data containing all worldwide "procedures performed using Intuitive's da Vinci Surgical System from January 1, 2012 through December 31, 2021"²⁶ ("Intuitive Procedures data"). ²⁷ Below I list the fields relevant for my analysis as well as my understanding of these fields:
 - Hospital Name: Facility name
 - Account ID: Facility identifier

¹⁹ Intuitive-00701322.

Intuitive Surgical, Inc. Responses to Rebotix Repair, LLC's Data Questions, July 10, 2021, at p. 5.

²¹ *Id*.

²² *Id*.

²³ *Id*.

²⁴ *Id.* at p. 6.

²⁵ *Id*

²⁶ Intuitive Surgical, Inc. Responses to Class Plaintiffs' Data Questions, at p. 11.

²⁷ Intuitive-00706097.

• IDN: Integrated Delivery Network identifier, i.e., health system identifier

• Country: Country

• Category: Procedure category

• Procedure Subject: Procedure Subject

da Vinci Procedure Volume: Number of procedures performed using the da Vinci Surgical
 System

• System ID: system platform type

4. IQVIA Procedures Data

7. I use data produced by Intuitive where Intuitive routinely integrates its own data that tracks da Vinci surgical procedures at U.S. hospitals with data from IQVIA, a healthcare-focused market research vendor, which provides estimates of the specific volumes of laparoscopic and open surgery procedures at these hospitals ("IQVIA data"). These data cover the period from 2012 through 2021. Below I list the fields relevant for my analysis as well as my understanding of these fields:

• Account Name: Facility name

• Account ID: Facility identifier

• Current IDN: Integrated Delivery Network identified, i.e., health system identifier

• Procedure Group: Procedure group

• Category: Procedure category

 Adjusted Total Volume: Total surgical volume across da Vinci, laparoscopic, and open procedures²⁹

Intuitive-00706098. The IQVIA data does not track a small number of procedure categories where da Vinci is used, including "Cardiac" and "Head and Neck" procedures.

²⁹ "Adjusted Total Volume is the total surgical volume across da Vinci, laparoscopic, and open, typically provided by IQVIA. In select instances, total volume equals the da Vinci volume if

- Adjusted Open Volume: "Surgical volume for open surgeries"
- da Vinci Volume: "Number of da Vinci surgical procedures" 31
- Lap Volume: "Number of laparoscopic, non-da Vinci surgical procedures" 32

B. DATA PREPARATION

1. Linking Customers between the I&A Transactions and Procedures Data

- 8. When analyzing Intuitive's instrument pricing expressed per procedure, I integrate information from multiple sources identified above. To do this, I create a crosswalk between customer identifiers in the I&A Transactions data and those in the Intuitive and IQVIA Procedures data by utilizing customer information in the System Transactions data as a bridge between these datasets. Customers in the I&A Transactions data are identified by "Customer" number and "Ship to Party" number. Customers in the IQVIA and Intuitive Procedures data are identified by "Account ID", which is also referred to as the "Netsuite ID". The Systems Transactions data contains all three identifiers.
- 9. First, I use "Customer" in the I&A data and "Customer Number" in the Systems data to match customers between these datasets.³³ I am able to link the majority of customers using this approach. Second, I use "Ship to Party" number in the I&A and System Transactions data to match customers that are associated with leasing transactions, because these transactions are assigned a special customer number that corresponds to a leasing company and cannot be mapped to a specific hospital. Third, I add to the crosswalk some additional customer identifiers

the da Vinci volume is greater than the total surgical volume in IQVIA." Intuitive Surgical, Inc. Responses to Class Plaintiffs' Data Questions, at p. 12.

³⁰ "In select instances when the da Vinci volume exceeds the total volume for minimally invasive surgeries, open surgeries is calculated as the difference between total volume and the da Vinci volume." *Id*.

³¹ *Id*.

³² *Id*.

³³ Intuitive Surgical, Inc. Responses to Restore's Data Questions, July 10, 2021, at p. 4.

that I am not able to match through the first two steps, due to changes in the "Customer" and "Ship to Party" records over time.

10. The resulting crosswalk allows me to link instrument sales to customers from the IQVIA and Intuitive Procedures data using "Netsuite ID". The matching process described above results in a customer crosswalk that captures approximately 91% of total I&A sales from Q1 2012 through Q4 2021. Customers not found in the Systems data are primarily those who purchased their system(s) prior to the period covered by the Systems data (i.e., before 2012). Similarly, the matched customers account for approximately 96% of the da Vinci procedures in IQVIA data and 94% of the da Vinci procedures in the Intuitive data.

2. Calculating Average Selling Price for a da Vinci model Xi

- 11. To calculate average price per system, I start with the System Transactions data from 2014 through 2021.³⁴ I then isolate system sales transactions and remove the following:³⁵
 - Transactions that occur outside of the United States
 - System leases
 - System trade-ins
 - System upgrades
 - Transactions with no system revenue and no system quantities
- 12. Following this filtering, I calculate the weighted average price per system as the sum of "Total System Revenue USD" over the sum of "System Qty" in a given year. ³⁶ I do this separately for each type of console, single versus dual.

The Xi model was launched in 2014.

The process for identifying new system sales versus leases follows the description provided in Intuitive Surgical, Inc. Responses to Restore's Data Questions, July 10, 2021, at p. 2.

As discussed in my report, I present prices for the model Xi which accounts for 93% of system revenue during the period after applying the filtering identified above.

3. Calculating Average Instrument Prices Expressed Per Procedure and Per Use

- 13. My analysis of instrument pricing uses a combination of the I&A Transactions data, IQVIA Procedures data, and Intuitive Procedures data. In preparing these data for analysis, I remove the following types of instrument sales transactions from the combined dataset:
 - Transactions that are recorded as "ISI REBATE PROGRAM" in the "Material Description" field;
 - Transactions with zero sales quantity;
 - Transactions other than instrument sales (i.e., Accessories);
 - Transactions for units that are only partially used before being returned;³⁷
 - Transactions associated with Ion instruments; and
 - Transactions associated with training instruments. 38
- 14. Following this approach, I aggregate procedure totals from the hospital level to the IDN (hospital network) level to account for customers which operate as a broader hospital network having multiple hospitals that utilize the da Vinci system. I do this using either the recorded hospital IDN/network name (based on the Current IDN field) or Netsuite_ID for customers that are not identified as being part of a broader network in the data.
- 15. I then categorize all customers into two groups (high and low) based on their relative share of da Vinci procedures out of total surgical procedures performed by the customer across modalities in 2021, which I define as the sum of da Vinci, laparoscopic, and open procedures. Specifically, I assign a customer to a "high" group if its da Vinci share in 2021 is above the median value, and I assign them to a "low" group if their da Vinci share is below the median value. In the supplemental analyses below, I also use the 75th percentile and 90th percentile of da Vinci share

These are recorded with a value of "USE" in the "Unit" field. *See* Intuitive Surgical, Inc. Responses to Rebotix Repair, LLC's Data Questions, July 10, 2021, questions 6 and 7 at pp. 3-4.

Training instruments can be identified based on their "Material Num" field suffix. Intuitive Surgical, Inc. Responses to Class Plaintiffs' Data Questions, at p. 2.

as a delineation for assigning customers to low- and high-share groups. This categorization assigns customers into one of the groups for all years from 2012-2021 based on the customer's share in 2021.

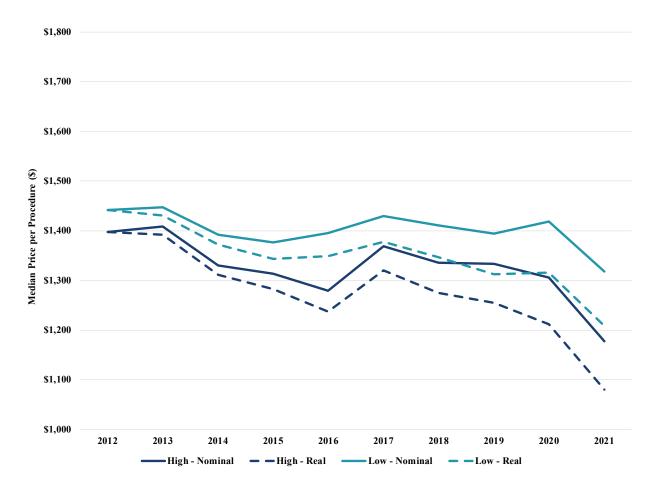
- 16. I calculate two price metrics: instrument price per procedure and instrument price per use. I calculate the price per procedure for each customer as the sum of its "Net Sales" over the sum of its da Vinci procedures in a given year based on the Intuitive Procedures data. I then keep observations with positive prices, remove the 1st and 99th percentiles of prices across 2012-2021 and calculate the median price in each year.³⁹
- 17. To calculate the instrument price per use, I first determine the number of uses for each instrument using the field called "Number Of Uses (if Each) or Qty per Box (if Box)." When the number of uses is not available for a given product, I use the median number of uses calculated for each base material and unit type. I then multiply the number of uses for each instrument by the "Sales Qty" field. Second, I omit transactions with zero dollars in gross sales as well as instruments with less than 100 total units sold across the full period 2012-2021. Following the steps above, I aggregate "Net Sales" and product uses to the year and base material level, and keep observations with positive net sales and sales quantities. I then calculate the weighted average instrument price per use as the sum of "Net Sales" over the sum of uses in a given year.

C. SUPPLEMENTAL INSTRUMENT PRICING ANALYSES

18. The figures below present the pricing trends for low- and high-share groups of customers defined when using the 75th and 90th percentiles of da Vinci procedure share (da Vinci share) instead of the median.

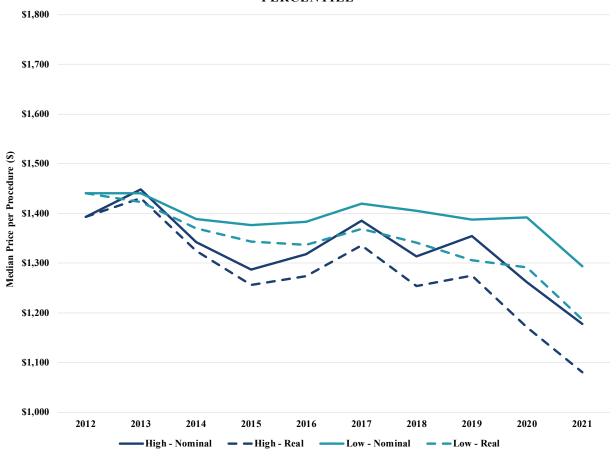
The results are similar when I do not apply the filter to remove the 1st and 99th percentiles of prices per procedure.

FIGURE A-1 – MEDIAN PRICE PER PROCEDURE – HIGH DA VINCI SHARE ABOVE 75^{TH} PERCENTILE



Sources and Notes: Prices per procedure relate net sales amounts calculated from Intuitive's I&A sales data to Intuitive's procedures data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the 75th percentile of da Vinci share of total procedures (55 percent).

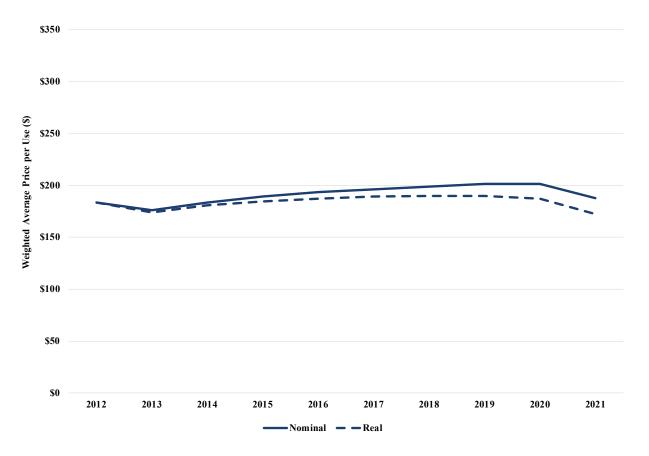
FIGURE A-2 – MEDIAN PRICE PER PROCEDURE – HIGH DA VINCI SHARE ABOVE 90^{TH} PERCENTILE



Sources and Notes: Prices per procedure relate net sales amounts calculated from Intuitive's I&A sales data to Intuitive's procedures data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the 90th percentile of da Vinci share of total procedures (69 percent).

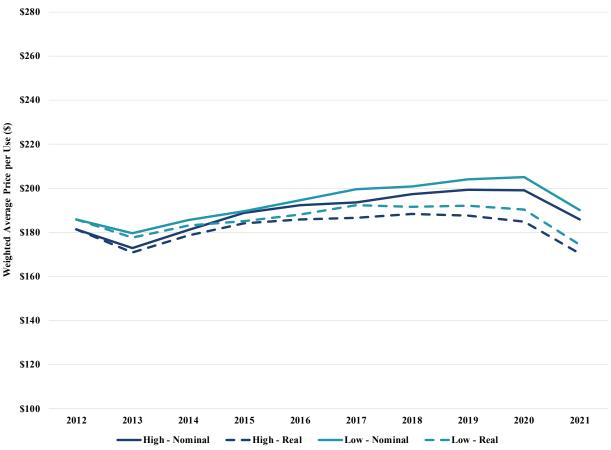
19. The figure below presents the instrument pricing trend calculated on the per use basis.

FIGURE A-3 – WEIGHTED AVERAGE PRICE PER USE



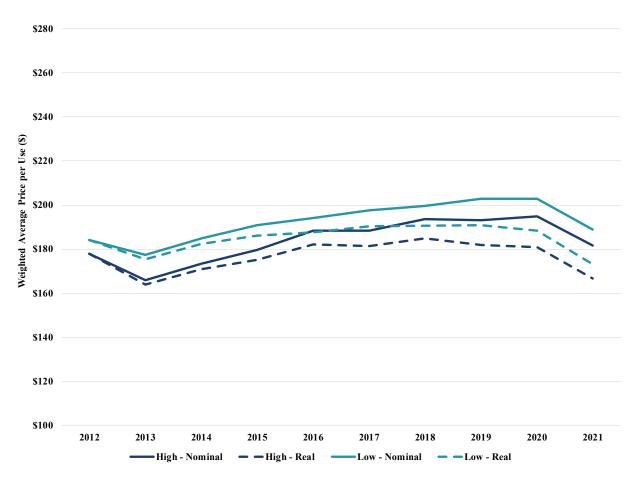
Sources and Notes: Prices per use relate net sales amounts to the number of uses for sold instruments as calculated from Intuitive's I&A sales data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391).

FIGURE A-4 – WEIGHTED AVERAGE PRICE PER USE – HIGH DA VINCI SHARE ABOVE 50^{TH} PERCENTILE



Sources and Notes: Prices per use relate net sales amounts to the number of uses for sold instruments as calculated from Intuitive's I&A sales data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the 50th percentile of da Vinci share of total procedures (40 percent).

FIGURE A-5 – WEIGHTED AVERAGE PRICE PER USE – HIGH DA VINCI SHARE ABOVE 75^{TH} PERCENTILE



Sources and Notes: Prices per use relate net sales amounts to the number of uses for sold instruments as calculated from Intuitive's I&A sales data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the 75th percentile of da Vinci share of total procedures (55 percent).

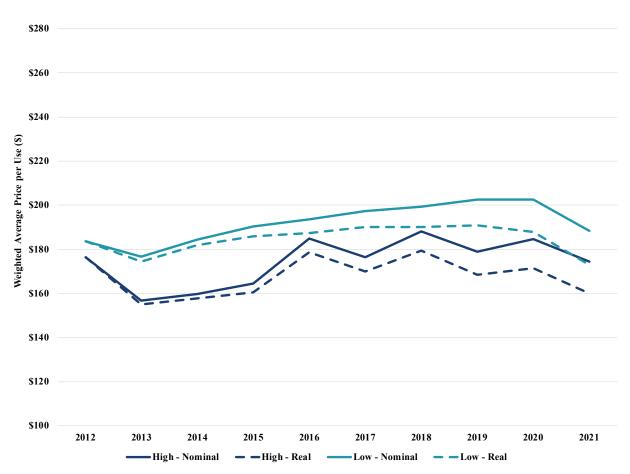


FIGURE A-6 – WEIGHTED AVERAGE PRICE PER USE – HIGH DA VINCI SHARE ABOVE 90^{TH} PERCENTILE

Sources and Notes: Prices per use relate net sales amounts to the number of uses for sold instruments as calculated from Intuitive's I&A sales data. Current dollars are converted to constant 2012 dollars using the producer price index for medical equipment and supplies manufacturing PPI (PCU33913391). Customers are divided into low and high groups based on the 90th percentile of da Vinci share of total procedures (69 percent).

20. I also use a regression model to analyze the price trends while controlling for changes in instrument mix over time. More specifically, I estimate the following regression model:

$$p_{it} = \alpha + \beta_t \lambda_t + \gamma_i D_i + \varepsilon_{it}$$

where p_{it} is the price per use for base material i and year t following the calculations detailed in Section B.3 above, λ_t is an indicator variable for year t, D_i is an indicator variable for base material i which allows me to control for changes in instrument mix over time, and ε_{it} is the error term. The price per use regressions are weighted by the total number of uses for each base material-year.

21. I present my regression results estimated using all instruments in Table A-1. Consistent with the price trends shown in Figure A-3, I find that the net price per use has not increased over the period and has in fact has slightly decreased in the last two years. This confirms that my assessment of Intuitive's instrument pricing does not change, after controlling for instrument mix changes over time.

TABLE A-1 - REGRESSION ANALYSIS OF INSTRUMENT PRICE TRENDS OVER TIME

	Net Price Per Use [A]
Year = 2013	-1.067
	(1.125)
Year = 2014	-1.345
	(1.129)
Year = 2015	-1.162
	(1.117)
Year = 2016	-0.981
	(1.100)
Year = 2017	-1.051
	(1.091)
Year = 2018	-1.111
	(1.092)
Year = 2019	-1.006
	(1.101)
Year = 2020	-2.095*
	(1.138)
Year = 2021	-4.799***
	(1.200)
Constant	194.4***
	(0.895)
# of Unique Base Materials	160
Observations	1047
R2	0.998

Standard errors in parentheses

Notes: Prices per use relate net sales amounts to instrument uses as calculated from Intuitive's I&A sales data. Observations are weighted by the total number of uses for each base material-year.

22. In Table A-2, I report the regression results estimated using S/Si instruments only. Similar to the price trend for all instruments, I find that the net price per use remains statistically flat. This

^{***} p<0.01, ** p<0.05, * p<0.1

confirms that, controlling for instrument mix changes, Intuitive has not been increasing S/Si instrument prices over time.

TABLE A-2 - REGRESSION ANALYSIS OF S/SI INSTRUMENT PRICE TRENDS OVER TIME

	Net Price Per Use [A]
Year = 2013	-1.080
	(1.024)
Year = 2014	-1.387
	(1.040)
Year = 2015	-1.304
	(1.069)
Year = 2016	-1.127
	(1.089)
Year = 2017	-1.222
	(1.121)
Year = 2018	-1.367
	(1.187)
Year = 2019	-1.214
	(1.320)
Year = 2020	-1.199
	(1.737)
Year = 2021	1.466
	(2.725)
Constant	197.1***
	(0.758)
# of Unique Base Materials	77
Observations	620
R2	0.997

Standard errors in parentheses

Notes: Prices per use relate net sales amounts to instrument uses as calculated from Intuitive's I&A sales data. Observations are weighted by the total number of uses for each base material-year.

D. SUPPLEMENTAL SUBSTITUTION ANALYSES

23. Table A-3 depicts the changes in relative shares among three surgical modalities over the period between 2012 and 2021 for hospitals that used the da Vinci Surgical System as of 2021. In column [A], I perform this analysis at the individual hospital level. In column [B], I aggregate

^{***} p<0.01, ** p<0.05, * p<0.1

procedures to the IDN level for hospitals that belong to the same hospital network and have greater than zero da Vinci procedures.

TABLE A-3 – COMPOSITION OF MODALITY CHANGES FOR DA VINCI CUSTOMERS IN 2021

		Hospital Level [A]	IDN Level [B]
All Customers			
Number of Customers	[1]	2,027	649
Avg. %-Point Change in da Vinci Share	[2]	0.35	0.32
Avg. %-Point Change in Laparoscopic Share	[3]	-0.18	-0.17
Avg. %-Point Change in Open Share	[4]	-0.18	-0.15
Customers Without Change in da Vinci Share			
Number of Customers	[5]	9	1
% of All Customers	[6]	0.44%	0.15%
Customers With da Vinci Share Increase			
Number of Customers	[7]	1,936	626
% of All Customers	[8]	95.51%	96.46%
Avg. %-Point Change in da Vinci Share	[9]	0.37	0.33
Avg. %-Point Change in Laparoscopic Share	[10]	-0.19	-0.18
Avg. %-Point Change in Open Share	[11]	-0.18	-0.15
Customers With da Vinci Share Decrease			
Number of Customers	[12]	82	22
% of All Customers	[13]	4.05%	3.39%
Avg. %-Point Change in da Vinci Share	[14]	-0.12	-0.05
Avg. %-Point Change in Laparoscopic Share	[15]	0.12	0.09
Avg. %-Point Change in Open Share	[16]	-0.01	-0.04

Sources and Notes:

Intuitive-00706098.xlsx, "IQVIA" sheet.

This table depicts changes in relative shares among three surgical modalities over the period between 2012 and 2021 for hospitals that used the da Vinci system as of 2021.

[B]: For hospitals without IDNs, figures reflect hospital-level information.

[6]: [5]/[1].

[8]: [7]/[1].

[13]: [12]/[1].

24. In both analyses, I identify the number of customers that had no change, an increase, or a decrease in its da Vinci share. I then compute the average percentage point change in shares for

da Vinci, open surgery, and laparoscopic modalities among customers within each group. The analysis presented in the table below is based on procedure categories that are tracked by the IQVIA data.

25. In Tables A-4 and A-5, I use the IQVIA data for 2021 to summarize the relative proportions of procedure volumes by comparing the extent of procedures performed with the da Vinci system versus those performed through laparoscopic and open surgery. As a sensitivity to the tables presented in my report, these examine the shares on a weighted-average basis, instead of using unweighted average. In Table A-4, I look at all hospitals that performed at least one surgery of the procedure type during 2021, regardless of modality. In Table A-5, I focus only on hospitals that utilized the da Vinci system during 2021. The shares presented in both tables are weighted by the hospital's procedure volumes.

TABLE A-4 – WEIGHTED AVERAGE MODALITY SHARE OF PROCEDURE CATEGORY AT HOSPITALS PERFORMING ANY SURGERIES IN THESE CATEGORIES DURING 2021

Category & Procedure Type	# of Hospitals Performing Procedure	% of These Hospitals Using da Vinci	da Vinci Share	Laparoscopic Share	Open Share
-	[A]	[B]	[C]	[D]	[E]
Colorectal					
Colon	3,603	49%	33%	11%	56%
Rectal	1,733	59%	42%	11%	47%
General Surgery					
Bariatric	2,701	33%	29%	55%	16%
Cholecystectomy	4,209	42%	17%	76%	7%
Hernia	4,262	47%	34%	16%	50%
HPB	1,119	37%	26%	8%	66%
Foregut	2,784	53%	25%	71%	3%
Gynecology					
Hysterectomy	3,622	50%	51%	33%	17%
Thoracic	2,074	36%	37%	37%	26%
Urology					
Nephrectomy	2,215	62%	51%	25%	23%
Prostatectomy	2,055	70%	84%	13%	3%

Sources and Notes:

Based on IQVIA data for 2021. "Cardiac" and "Head and Neck" categories are omitted because they are not tracked in the IQVIA data and account for less than 1 percent of all da Vinci procedures in 2021 based on Intuitive-00706097. "HPB" stands for Hepato-Pancreato-Biliary surgery, which involves surgery of the liver, pancreas and biliary system.

[A]: 4,452 total hospitals in the IQVIA dataset performed at least one surgery in 2021.

TABLE A-5 – WEIGHTED AVERAGE MODALITY SHARE OF PROCEDURE CATEGORY AT HOSPITALS PERFORMING DA VINCI SURGERIES DURING 2021

Category & Procedure Type	# of Hospitals Performing Procedure	da Vinci Share	Laparoscopic Share	Open Share
	[A]	[B]	[C]	[D]
Colorectal				
Colon	2,015	39%	8%	53%
Rectal	1,380	45%	9%	45%
General Surgery				
Bariatric	1,813	33%	51%	16%
Cholecystectomy	2,054	22%	71%	7%
Hernia	2,066	42%	13%	45%
HPB	937	27%	7%	66%
Foregut	1,859	29%	68%	4%
Gynecology				
Hysterectomy	2,000	56%	28%	15%
Thoracic	1,566	40%	36%	24%
Urology				
Nephrectomy	1,698	55%	23%	22%
Prostatectomy	1,640	87%	10%	2%

Sources and Notes:

Based on IQVIA data for 2021. "Cardiac" and "Head and Neck" categories are omitted because they are not tracked in the IQVIA data and account for less than 1 percent of all da Vinci procedures in 2021 based on Intuitive-00706097. "HPB" stands for Hepato-Pancreato-Biliary surgery, which involves surgery of the liver, pancreas and biliary system.

[A]: 2,076 total hospitals in the IQVIA dataset performed at least one da Vinci surgery in 2021.

EXHIBIT A Smith Curriculum Vitae

Loren K. Smith

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EDUCATION

January 2006 University of Virginia, Ph.D. in Economics

May 2001 University of Virginia, M.A. in Economics

December 1996 Mississippi State University, B.B.A. in Marketing, Magna Cum Laude

PROFESSIONAL EXPERIENCE

April 2020–Present Principal, The Brattle Group, Washington, DC

April 2016–March 2020 Executive Vice President, Compass Lexecon, Washington, DC

Senior Vice President, April 2014 – March 2016

Vice President, April 2013 - March 2014

September 2005-March 2013 Staff Economist, U.S. Federal Trade Commission, Washington, DC

June 2002–May 2005 Instructor, University of Virginia, Charlottesville, VA

Courses: Intermediate Microeconomics

September 1999–May 2001 Teaching Assistant, University of Virginia, Charlottesville, VA

Courses: Principles of Microeconomics, Principles of Macroeconomics, Graduate Math-Economics, Graduate

Econometrics, Intermediate Microeconomics

Research Assistant, University of Virginia, Charlottesville, VA

Edgar Olsen, Charles Holt

FIELDS OF SPECIALIZATION

Antitrust and Competition Economics Applied Microeconomics Industrial Organization Applied Econometrics

TESTIMONY

Testimony as Economic Expert on behalf of Intuitive Surgical, In Re: *Rebotix Repair LLC v. Intuitive Surgical, Inc.,* in the United States District Court Middle District of Florida Tampa Division, Case No. 8:20-cv-02274, Deposition: November 3, 2021.

Testimony as Economic Expert on behalf of Intuitive Surgical, In Re: *Restore Robotics LLC, and Restore Robotics Repair LLC v. Intuitive Surgical, Inc.,* in the United States District Court Northern District of Florida Panama City Division, Case No. 5:19-cv-55, Deposition: October 21, 2021.

Testimony as Economic Expert on behalf of the Federal Trade Commission, In Re: *Federal Trade Commission and Commonwealth of Pennsylvania v. Thomas Jefferson University and Albert Einstein Healthcare Network*, In the Eastern District Court of Pennsylvania, Case No. 2:20-cv-01113-GJP, Deposition: August 26, 2020; Trial: September 15 and 16, and October 1, 2020.

REPORTS

Expert Report of Loren K. Smith, In Re: *United States of America, ex. rel. Sarah Behnke v. CVS Caremark Corporation et al.*, in the United States District Court Eastern District of Pennsylvania, Civil Action No. 2:14-cv-00824-MSG, December 9, 2022.

Expert Report of Loren K. Smith, In Re: *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, in the United States District Court Northern District of California, Case No. 3:21-cv-03496-VC, December 2, 2022.

Expert Reports of Loren K. Smith, In Re: *Restore Robotics LLC, and Restore Robotics Repair LLC v. Intuitive Surgical, Inc.,* in the United States District Court Northern District of Florida Panama City Division, Case No. 5:19-cv-55; Counterclaims Damages: August 20, 2021, Rebuttal Antitrust: September 27, 2021, Supplemental Rebuttal Report Antitrust Damages: December 23, 2022.

Expert Reports of Loren K. Smith, In Re: *Rebotix Repair LLC v. Intuitive Surgical, Inc.,* in the United States District Court Middle District of Florida Tampa Division, Case No. 8:20-cv-02274; Counterclaims Damages: July 26, 2021, Rebuttal Antitrust Merits and Rebuttal Antitrust Damages: August 30, 2021.

"Brief of Antitrust Economists as Amici Curiae in Support of Defendants-Appellants Urging Reversal," In the United States Court of Appeals for the Sixth Circuit; *St. Luke's Hospital et al., v. ProMedica Health System, Inc. et al.*; On Appeal from the United States District Court for the Northern District of Ohio; No. 3:20-cv-02533; March 1, 2021.

Expert Reports of Loren K. Smith, In Re: *Federal Trade Commission and Commonwealth of Pennsylvania v. Thomas Jefferson University and Albert Einstein Healthcare Network*, In the Eastern District Court of Pennsylvania, Case No. 2:20-cv-01113-GJP, Report: July 23, 2020, Rebuttal Report: August 20, 2020.

Expert Report of Loren K. Smith, In Re: *United States of America and the State of North Carolina v. The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System*, In the District Court of North Carolina, Case No. 3:16-cv-00311-RJC-DCK, October 5, 2018.

Report to Congress Under Section 319 of the Fair and Accurate Credit Transactions Act of 2003, (with Beth Freeborn and Peter Vander Nat), December 2012.

SELECTED CONSULTING WORK RELATED TO ANTITRUST INVESTIGATIONS

Submitted a co-authored paper to the U.S. Department of Justice on the competitive implications of a vertical acquisition in the productivity software space (2022).

Submitted a co-authored paper to the U.S. Federal Trade Commission on the competitive implications of a merger in the specialty pharmacy services industry (2022).

Presented to the U.S. Department of Justice on the economic implications of a consumer products merger (2021).

Provided written and oral presentations to the U.S. Federal Trade Commission related to a proposed acquisition of a pipeline prescription pharmaceutical product (2020).

Presented and provided multiple written submissions to the U.S. Federal Trade Commission related to a proposed merger of two major hospital systems (2020).

Presented and provided multiple written submissions to the U.S. Federal Trade Commission related to a proposed merger of polyurethane foam manufacturers (2019).

Presented to the U.S. Federal Trade Commission related to a merger that, in part, proposed to combine existing and pipeline branded drugs with similar indications (2019).

Presented and provided a written submission to the U.S. Federal Trade Commission related to the proposed merger of branded pharmaceutical manufacturers (2019).

Presented to the U.S. Federal Trade Commission related to a proposed hospital merger (2018).

Submitted a white paper and gave a presentation to the U.S. Federal Trade Commission related to a proposed merger of factory-built home manufacturers (2018).

Presented to the U.S. Federal Trade Commission related to a proposed merger of food manufacturers (2017).

Presented to the U.S. Federal Trade Commission related to a proposed merger of personal and home cleaning manufacturers (2017).

Presented to the U.S. Department of Justice related to accusations of anticompetitive

exclusionary conduct against a hospital system (2017).

Provided economic and econometric analysis of alleged damages, the results of which were used in a mediation that reached a favorable settlement (2016–2017).

Submitted a coauthored white paper and participated in presentations to the U.S. Federal Trade Commission related to accusations of anticompetitive exclusionary conduct against a manufacturer of medical device inputs (2015-2016).

Gave multiple presentations to the U.S. Federal Trade Commission related to a proposed merger of retail chains (2014).

Provided economic analysis related to the proposed acquisition of two community hospitals. The results were submitted to the U.S. Federal Trade Commission (2014).

Developed empirical analyses that demonstrated a lack of competitive interaction with a proposed merger partner. The results were submitted to the U.S. Federal Trade Commission (2014).

Coauthored two white papers that were submitted to the U.S. Department of Justice related to a proposed hospital acquisition (2013).

Coauthored three white papers that were submitted to the U.S. Federal Trade Commission related to a proposed acquisition in the supermarket industry (2013).

Coauthored a white paper that was submitted to the U.S. Federal Trade Commission related to a proposed acquisition in the retail auto parts industry (2013).

As economic expert for the U.S. Federal Trade Commission, evaluated the likely competitive effects of a merger of data service providers (2011).

LITIGATION SUPPORT WORK

In support of Robert Willig and Jonathan Orszag, developed economic and econometric evidence, and assisted in the preparation of expert reports and testimony on behalf of the Defendants in Re: *Sidibe, et al. v. Sutter Health*, Case No. 3:12-cv-04854.

In support of Robert Willig and with Bryan Keating, developed economic and econometric evidence, and assisted in the preparation of expert reports and testimony on behalf of the Defendants in Re: *UFCW & Employers Benefit Trust v. Sutter Health, et al.*, Case No. CSG 14-538451.

In support of Mark Israel and with Theresa Sullivan, developed economic and econometric evidence on behalf of the U.S. Federal Trade Commission in Re: *Federal Trade Commission et al. v. Draftkings, Inc. and FanDuel Limited*, Civil Action No. 17-cv-1195 (KBJ).

In support of Jonathan Orszag, developed economic theories and assisted in the preparation of an expert report and deposition testimony on behalf of Plaintiffs in Re: *Innovation Ventures, LLC v. Nutrition Science Laboratories, LLC et al.*, Case No. 2:12-cv-13850.

In support of Mark Israel and with Theresa Sullivan, developed merger simulations and assisted in preparation of expert reports and testimony on behalf of Defendants in Re: *U.S. and Plaintiff States v. Anthem and Cigna*, Civil Action No. 1:16-cv-01493.

In support of Robert Willig, developed economic and econometric evidence, and assisted in preparation of expert reports and testimony on behalf of the Defendants in Re: *Methodist Health Services Corporation v. OSF Healthcare System*, Civil Action No. 1:13-dv-01054-SLD-IEH.

In support of Robert Willig and with Bryan Keating, developed economic and econometric evidence, and assisted in preparation of expert reports and testimony on behalf of the Defendants in Re: *Federal Trade Commission and Commonwealth of Pennsylvania vs. Penn State Hershey Medical Center and PinnacleHealth System*, Civil Action No. 1:15-cv-02362.

In support of Mark Israel, developed economic and econometric evidence, and assisted in the preparation of expert reports and testimony on behalf of the U.S. Federal Trade Commission in Re: *Federal Trade Commission et al. v. Sysco Corporation and USF Holding Corp.*, Civil Action No. 15-cv-00256 (APM).

PUBLICATIONS AND OTHER PUBLICLY AVAILABLE PAPERS

"Looking Behind the Mask: Economic Analyses of Physician Group Transactions" (with Josephine Duh, Daniel Fanaras, and Bogdan Genchev), 2022, American Health Law Association, available at https://www.americanhealthlaw.org/content-library/publications/briefings/f5e6c787-59d0-4aea-92c0-946ee4de1399/Looking-Behind-the-Mask-Economic-Analyses-of-Physi

"Trends in Consumer Shopping Behavior and their Implications for Retail Grocery Merger Reviews" (with Dimitri Dimitropoulos and Renée Duplantis), 2021, *Competition Policy International*

"4 Economic Takeaways From 6th Circ. ProMedica Decision" (with Josephine Duh), 2021, *Law360*, available at https://www.law360.com/articles/1438179/4-economic-takeaways-from-6th-circ-promedica-decision

"The Other Side of the Coin: Complementarity in Mergers of Multiproduct Firms" (with Craig Minerva and Peter Herrick), 2021, American Bar Association's *Antitrust Magazine*, available at https://www.americanbar.org/groups/antitrust_law/publications/antitrust-magazine-online/2021/october/the-other-side-of-the-coin/

"The Competitive Implications of Private Label Mergers," (with Matt Schmitt), 2021, American Bar Association's *Antitrust Law Journal*, available at https://www.americanbar.org/digital-asset-abstract.html/content/dam/aba/publishing/antitrust_law_journal/alj-833/schmitt-smith.pdf

"Understanding the Econometric Tools of Antitrust – With No Math!" (with Michael Cragg and Charles Gibbons), 2021, American Bar Association's *Antitrust*, available at https://www.americanbar.org/groups/antitrust_law/publications/antitrust_magazine/2021/atmag-spring2021-vol35-no2/

(*Concurrences* and the George Washington University Law School's Competition Law Center 2021 Antitrust Writing Awards Winner – Best Business Articles: Economics)

"Clarifying Bundle Markets and Distinguishing Them from Cluster Markets" (with Kevin Hahm), 2021, American Bar Association's *The Antitrust Source*, available at https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/2021/feb-2021/atsource-feb2021-full.pdf

"The Use of Econometrics in Merger Reviews" (with Christopher R. Rybak), 2020, American Bar Association's *Economics Committee Spring Newsletter*, available at https://www.americanbar.org/digital-asset-abstract.html/content/dam/aba/administrative/antitrust_law/aba-economics-committee-newsletter-spring2020.pdf

"Platforms, Entry, and Innovation," (with Bryan Keating), 2019, Comment to Federal Trade Commission Hearings Announcement (Docket ID FTC-2019-0032), available at https://www.regulations.gov/document?D=FTC-2019-0032-0016

"Unilateral Effect Analysis of Health Care Markets," *Economics of Health Care Mergers & the Pharmaceutical Industry* (an ALHA Antitrust Practice Group Toolkit), 2019, available at

https://www.healthlawyers.org/Members/PracticeGroups/Antitrust/Pages/default.aspx

"Do Retail Mergers Affect Competition? Evidence from Grocery Retailing," (with Dan Hosken and Luke M. Olsen), *Journal of Economics and Management Strategy*, Vol. 27, Iss. 1, pp. 3-22, Spring 2018.

"Toward a More Complete Treatment of Efficiencies in Merger Analysis: Lessons from Recent Challenges," (with Jonathan M. Orszag), *The Antitrust Source*, Vol. 16, No. 1, October 2016.

"The Prominence of Market Definition in Antitrust Evaluation and Litigation," (with Maria Stoyadinova), *Global Antitrust Economics: Current Issues in Antitrust Law and Economics*, Eds. Douglas H. Ginsburg and Joshua D. Wright, New York: Institute of Competition Law, 2016, pp. 103-116.

"Can Entry or Exit Event Studies Inform Horizontal Merger Analysis? Evidence from Grocery Retailing," (with Dan Hosken and Luke M. Olsen), *Economic Inquiry*, Vol. 54, Iss. 1, pp. 342-360, January 2016.

"Dynamics in a Mature Industry: Entry, Exit, and Growth of Big-Box Grocery Retailers," (with Dan Hanner, Dan Hosken, and Luke M. Olsen), *Journal of Economics and Management Strategy*, Vol. 24, Iss. 1, pp. 22-46, Spring 2015.

"Dynamics and Equilibrium in the Market for Commercial Aircraft," *Journal of Applied Econometrics*, Vol. 27, Iss. 1, pp. 1-33, February 2012.

"New Market Policy Effects on Used Markets: Theory and Evidence," *The B.E. Journal of Economic Analysis & Policy*, Vol. 9, Iss. 1 (Topics), Article 32, July 2009.

AWARDS AND HONORS

Who's Who Legal Thought Leaders - Competition Economists, 2023

Lexology Client Choice Award - Competition Economists, 2022

Who's Who Legal Competition - Competition Economists, 2019 - 2022

Who's Who Legal Competition: Future Leaders – Economists, 2017, 2018 (named one of the four "Most Highly Regarded" competition economists in North America in 2018)

Award for Outstanding Scholarship: for outstanding contributions to the economics literature and to the pursuit of scholarship at the Federal Trade Commission, 2012

Janet D. Steiger Award: for outstanding contributions to the Pay-for-Delay Team, Federal Trade Commission, 2012

Predoctoral Fellowship, Bankard Fund for Political Economy, University of Virginia, 2003-2004

Research Grant, Darden Business School, University of Virginia, 2002

Graduate Fellowship, University of Virginia, 1999–2002

MISCELLANEOUS

REFEREE

International Journal of Game Theory

International Journal of Industrial Organization

Economic Theory

Journal of Policy Analysis and Management

TEACHING

Full Courses:

Econonometrics – Johns Hopkins University, 2008

Intermediate Microeconomics – University of Virginia, 2002–2005

Mini Courses:

"Mergers" with Miguel de la Mano, Sean Ennis, and Nicolas Hill – Fordham Law School, 2012

"The Economics of Vertical Restraints" – GHV, Budapest, HU, 2010

"Quantitative Methods for Merger Investigation" with Keith Brand - CADE, Brasilia, BR, 2009

"Quantitative Methods for Antitrust Economists" – Competition Commission, Pretoria, ZA, 2007

"Introduction to Quantitative Methods for Antitrust Lawyers" – FTC, 2006, 2007, and 2008

PRESENTATIONS AND SEMINARS

Fordham Competition Law Institute – 49th Annual Conference on International Antitrust Law and Policy and Antitrust Economics Workshops, New York, NY

American Bar Association Antitrust Law Section and Health Law Section 2022 Antitrust in Healthcare Conference – Pharma Conduct Trends: Biosimilars, Generics, Pay-for-Delay, Arlington, VA

Concurrences 6th Global Antitrust Economics Conference – Acquisitions in High-Tech Space: Market Power and Innovation Issues, Webinar

Fordham Competition Law Institute – 48th Annual Conference on International Antitrust Law and Policy and Antitrust Economics Workshops, New York, NY

American Bar Association Antitrust Enforcement Priorities for the Healthcare Industry in 2021 Roundtable

Troutman Pepper – Antitrust Economics – The Building Blocks, Webinar

American Health Law Association Education Center – Antitrust Enforcement Update on Hospital and Health System Mergers, Webinar

Fordham Competition Law Institute -47^{th} Annual Conference on International Antitrust Law and Policy and Antitrust Economics Workshops, Webinar

Concurrences and Fordham University School of Law – Antitrust in Life Sciences Conference, Webinar

American Bar Association Economics Fundamentals, Webinar

15th Annual Kirkland Antitrust & Competition Institute – Intersection of Antitrust and Everything Else, Washington, DC

Pepper Hamilton's Annual Antitrust CLE Event, Philadelphia, PA

Fordham Competition Law Institute – 44th Annual Conference on International Antitrust Law & Policy, New York, NY

International Industrial Organization Conference, Boston, MA

GCR Live 2nd Annual Antitrust Litigation USA, New York, NY

The Global Antitrust Economics Conference – George Mason School of Law, Arlington, VA

Compass Lexecon – Economics Seminar, Washington, DC

Southern Economic Association - Annual Meeting, New Orleans, LA

University of Maryland – Econometrics Seminar, College Park, MD

Bureau of Labor Statistics - Empirical IO Seminar, Washington, DC

Drexel University – Industrial Organization Seminar, Philadelphia, PA

American Social Sciences Association - Annual Meeting, Philadelphia, PA

Southern Economic Association - Annual Meeting, New Orleans, LA

University of Virginia - Microeconomics Seminar, Charlottesville, VA

International Industrial Organization Conference, Chicago, IL

COMMUNITY ACTIVITIES

Tutor, Community Club, Washington, DC, 2007-2011

CITIZENSHIP

United States

EXHIBIT B Materials Considered

Bates-Stamped Documents [1] BB001260

- [2] CMR-00001108
- [3] Franciscan-00055779
- [4] Intuitive-00000316
- [5] Intuitive-00000339
- [6] Intuitive-00001237
- [7] Intuitive-00001639
- [8] Intuitive-00001788
- [9] Intuitive-00002138
- [10] Intuitive-00002937
- [11] Intuitive-00002537
- [12] Intuitive-00005135
- [13] Intuitive-00009717
- [14] Intuitive-00014989
- [15] Intuitive-00015458
- [16] [14] [15] 00001011
- [16] Intuitive-00021011[17] Intuitive-00029837
- [18] Intuitive-00038260
- [19] Intuitive-00045861
- [20] Intuitive-00065233
- [21] Intuitive-00118636
- [22] Intuitive-00122488
- [23] Intuitive-00143279
- [24] Intuitive-00154125
- [25] Intuitive-00186899
- [26] Intuitive-00203904
- [27] Intuitive-00213893 [28] Intuitive-00270554
- [29] Intuitive-00279920
- [30] Intuitive-00279923
- [31] Intuitive-00279958
- [32] Intuitive-00285709
- [33] Intuitive-00288971
- [34] Intuitive-00288975
- [35] Intuitive-00293400
- [36] Intuitive-00356654
- [37] Intuitive-00367019
- [38] Intuitive-00372053
- [39] Intuitive-00412740
- [40] Intuitive-00424372
- [41] Intuitive-00552533
- [42] Intuitive-00552535
- [43] Intuitive-00560028
- [44] Intuitive-00563748
- [45] Intuitive-00571076
- [46] Intuitive-00571081
- [47] Intuitive-00578133
- [48] Intuitive-00595405

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 145 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [49] Intuitive-00595406
- [50] Intuitive-00595407
- [51] Intuitive-00595408
- [52] Intuitive-00595409
- [53] Intuitive-00595410
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Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 146 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [100] Intuitive-00595456
- [101] Intuitive-00595457
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- [107] Intuitive-00595463
- [108] Intuitive-00595673
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- [114] Intuitive-00695232
- [115] Intuitive-00695233
- [116] Intuitive-00695234
- [117] Intuitive-00695236
- [118] Intuitive-00695237
- [119] Intuitive-00701321
- [120] Intuitive-00701322
- [121] Intuitive-00701343
- [122] Intuitive-00701343
- [123] Intuitive-00701742
- [124] Intuitive-00706089
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- [126] Intuitive-00706097
- [127] Intuitive-00706098
- [128] Intuitive-00840257 [129] Intuitive-00849019
- [130] Intuitive-00916726
- [131] Intuitive-01172898
- [132] Intuitive-01172899
- [133] Intuitive-01172908
- [134] Intuitive-01266032
- [135] Intuitive-01291299
- [136] Intuitive-01524447
- [137] Intuitive-02025757
- [138] Intuitive-02025758
- [139] Intuitive-02025759
- [140] Intuitive-02072146
- [141] Intuitive-02072147
- [142] LARKIN-00025488
- [143] REBOTIX001387
- [144] REBOTIX001387 001
- [145] REBOTIX040273 001
- [146] REBOTIX040277
- [147] REBOTIX046346
- [148] REBOTIX056093
- [149] REBOTIX062113
- [150] REBOTIX062114

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 147 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [151] REBOTIX162404
- [152] REBOTIX175326
- [153] Restore-00003932
- [154] SIS000035
- [155] SIS000046
- [156] SIS000047
- [157] SIS000051
- [158] SIS000097
- [159] SIS000167
- [160] SIS001637
- [161] SIS001684
- [162] SIS001981
- [163] SIS009067
- [164] SIS010647
- [165] SIS033520
- [166] SIS048254
- [167] SIS048255
- [168] SIS070889
- [169] SIS071311
- [170] SIS091199
- [171] SIS279094
- [172] SIS320176
- [173] SIS320922
- [174] SIS321300
- [175] SIS327629
- [176] VMC-00014375
- [177] VMC-00020652

Case Documents

- [178] Complaint, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 5:21-cv-03496-SK, May 10, 2021.
- [179] Defendant's Answer, Affirmative Defense, and Counterclaims and Exhibits, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 3:21-cv-03496-VC, December 14, 2021.
- [180] Intuitive Surgical, Inc. Responses to Rebotix Repair, LLC's Data Questions, July 10, 2021.
- [181] Intuitive Surgical, Inc. Responses to Restore's Data Questions, July 9, 2021.
- [182] Intuitive Surgical, Inc. Responses to Class Plaintiffs' Data Questions.
- [183] Intuitive Surgical, Inc. Responses to Class Plaintiffs' Follow-Up Data Questions.
- [184] Intuitive Surgical, Inc. Responses to Class Plaintiffs' Second Follow-Up Data Questions.

Depositions

- [185] Anthony McGrogan (in Rebotix) Deposition Transcript and Exhibits, June 7, 2021.
- [186] Bob DeSantis (in *Rebotix*) Deposition Transcript and Exhibits, May 27, 2021.
- [187] Bob DeSantis (in *Restore*) Deposition Transcript and Exhibits, May 20, 2021.
- [188] Chris Gibson (in *Rebotix*) Deposition Transcript and Exhibits, June 22, 2021.
- [189] Colin Morales 30(b)(1) Deposition Transcript and Exhibits, November 9, 2022.
- [190] David Robinson (in *Restore*) Deposition Transcript and Exhibits, May 5, 2021
- [191] David Rosa (in *Restore*) Deposition Transcript and Exhibits, May 19, 2021.
- [192] Dipen Maun Deposition Transcript and Exhibits, November 8, 2022.
- [193] Ed Harrich (in Rebotix) Deposition Transcript and Exhibits, May 24, 2021.
- [194] Glenn Vavoso (in *Rebotix*) Deposition Transcript and Exhibits, May 14, 2021.
- [195] Glenn Papit (in Rebotix) Deposition Transcript and Exhibits, June 2, 2021.

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 148 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [196] Greg Posdal (in *Restore*) Deposition Transcript and Exhibits, May 10, 2021.
- [197] Greg Posdal 30(b)(1) Deposition Transcript and Exhibits, November 1, 2022.
- [198] Greg Posdal 30(b)(6) Deposition Transcript and Exhibits, November 1, 2022.
- [199] Greta Bernier Deposition Transcript and Exhibits, November 7, 2022.
- [200] John Francis Deposition Transcript and Exhibits, October 14, 2022.
- [201] John Wagner Deposition Transcript and Exhibits, October 11, 2022.
- [202] Judith Schimmel Deposition Transcript and Exhibits, September 22, 2022.
- [203] Keith Johnson 30(b)(1) Deposition Transcript and Exhibits, October 27, 2022.
- [204] Keith Johnson 30(b)(6) Deposition Transcript and Exhibits, October 27, 2022.
- [205] Margaret Nixon Deposition Transcript and Exhibits, October 7, 2022.
- [206] Mark Early Deposition Transcript and Exhibits, November 6, 2022.
- [207] Mark Johnson (in Restore) Deposition Transcript and Exhibits, April 29, 2021.
- [208] Michael Burke Deposition Transcript and Exhibits, September 27, 2022.
- [209] Myriam Curet (in Restore) Deposition Transcript and Exhibits, May 7, 2021.
- [210] Nicky Goodson 30(b)(1) Deposition Transcript and Exhibits, October 27, 2022.
- [211] Nicky Goodson 30(b)(6) Deposition Transcript and Exhibits, November 16, 2022.
- [212] Paul Plomin Deposition Transcript and Exhibits, November 8, 2022.
- [213] Ricardo Estape Deposition Transcript and Exhibits, October 22, 2022.
- [214] Sandra Sosa-Guerro Deposition Transcript and Exhibits, September 23, 2022.
- [215] Stacey Donovan (in *Rebotix*) Deposition Transcript and Exhibits, May 27, 2021.
- [216] Stan Hamilton (in *Rebotix*) Deposition Transcript and Exhibits, June 4, 2021.
- [217] Todd Tourand Deposition Transcript and Exhibits, November 4, 2022.
- [218] Tyler McDonald (in Restore) Deposition Transcript and Exhibits, May 21, 2021.

Expert Reports

- [219] Expert Antitrust Merits Report of Loren K. Smith, Ph.D., *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021 and materials cited therein.
- [220] Expert Damages Rebuttal Report of Loren K. Smith, Ph.D., *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021 and materials cited therein.
- [221] Expert Damages Rebuttal Report of Loren K. Smith, Ph.D., *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, January 18, 2023 and materials cited therein.
- [222] Expert Rebuttal Report of Loren K. Smith, Ph.D., Restore Robotics LLC, Restore Robotics Repair LLC, and Clif Parker Robotics LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55, September 27, 2021 and materials cited therein.
- [223] Expert Report of Christy Foreman, MBE, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 3:21-cv-03496-VC, January 18, 2023.
- [224] Expert Report of Loren K. Smith, Ph.D., *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, July 26, 2021 and materials cited therein.
- [225] Expert Report of Loren K. Smith, Ph.D., Restore Robotics LLC and Restore Robotics Repair LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55, August 20, 2021 and materials cited therein.
- [226] Expert Report of Loren K. Smith, Ph.D., *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, December 2, 2022 and materials cited therein.
- [227] Expert Report of Richard F. Bero, CPA, CVA, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 3:21-cv-03496-VC, December 2, 2022.
- [228] Expert Report of Dr. Robert D. Howe, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc*, Case No. 3:21-cv-03496-VC, January 18, 2023.
- [229] Expert Report of Russell L. Lamb, Ph.D., Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 5:21-cv-03496, December 2, 2022.

Form 10-K

- [230] Asensus Surgical Form 10-K 2020
- [231] Intuitive Form 10-K 2000

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 149 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [232] Intuitive Form 10-K 2001
- [233] Intuitive Form 10-K 2010
- [234] Intuitive Form 10-K 2014
- [235] Intuitive Form 10-K 2019
- [236] Intuitive Form 10-K 2020
- [237] Intuitive Form 10-K 2021
- [238] Medtronic Form 10-K 2021

Literature and Textbooks

- [239] Agha, Riaz and Gordon Muir, "Does Laparoscopic Surgery Spell the End of the Open Surgeon?" *Journal of the Royal Society of Medicine* 96, No. 11 (2003): 544-546.
- [240] Azizian, Mahdi et al., "The da Vinci Surgical System," in *The Encyclopedia of Medical Robotics*, ed. Rajni Patel (New Jersey: World Scientific, 2018), 7.
- [241] Berk, Jonathan and Peter DeMarzo, *Corporate Finance, Fourth Edition* (Essex: Pearson Education Limited, 2017).
- [242] Carlton, Dennis W. and Jeffrey M. Perloff, *Modern Industrial Organization*, Fourth Edition (Boston: Pearson Education, Inc., 2015).
- [243] Choi, Jay Pil, "Mergers with Bundling in Complementary Markets," *Journal of Industrial Economics* 56, No. 3 (2008).
- [244] Crompton, Thomas, "Robotic Surgery Equipment Manufacturing," Industry Report OD4074 IBISWorld, December 2020.
- [245] Curran, Jack, "Medical Equipment Repair & Maintenance Services," Industry Report OD4964, IBISWorld, December 2021.
- [246] Dana Jr., James D. and Kathryn E. Spier, "Bundling and quality assurance," *The RAND Journal of Economics* 49, No. 1 (2018): 128-154.
- [247] Dhanani, Naila H. et al., "The Evidence Behind Robot-Assisted Abdominopelvic Surgery: A Systematic Review," *Annals of Internal Medicine* 174, No. 8 (2021): 1110-1117.
- [248] Estelami, Hooman, "Consumer Savings in Complementary Product Bundles," *Journal of Marketing Theory and Practice* 7, No. 3 (1999): 107-114.
- [249] Evans, David S. and Michael A. Salinger, "The Role of Cost in Determining When Firms Offer Bundles," *The Journal of Industrial Economics* 56, No. 1 (2008): 143-168.
- [250] Evans, David S. and Michael Salinger, "Why Do Firms Bundle and Tie? Evidence from Competitive Markets and Implications for Tying Law," Yale Journal on Regulation 22 (2005): 37.
- [251] Fisher, Franklin M. and John J. McGowan, "On the Misuse of Accounting Rates of Return to Infer Monopoly Profits," *American Economic Review* 73, No. 1 (1983): 82-97.
- [252] Gawande, Atul, "Two Hundred Years of Surgery," *The New England Journal of Medicine* 366 (2012): 1716-1723.
- [253] Kelley, William, "The Evolution of Laparoscopy and the Revolution in Surgery in the Decade of the 1990s," *Journal of the Society of Laparoendoscopic Surgeons* 12, No. 4 (2008): 351.
- [254] Kobayashi, Bruce, "Does Economics Provide a Reliable Guide to Regulating Commodity Bundling by Firms? A Survey of the Economic Literature," *Journal of Competition Law and Economics* 1, No. 4 (2005): 707-746.
- [255] Longmore, Sally Kathryn et al., "Laparoscopic Robotic Surgery: Current Perspective and Future Directions," *Robotics* 9, No. 2 (2020): 6.
- [256] Perloff, Jeffrey M., Microeconomics, Seventh Edition (Boston: Pearson Education, Inc., 2015).
- [257] Pindyck, Robert S. and Daniel L. Rubinfeld, *Microeconomics, Eighth Edition* (New Jersey: Pearson Education, Inc., 2013).
- [258] Pinto, Anna et al., "Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis," *BMJ Open* (2016): 1-23.
- [259] Sheetz, Kyle H., Jake Claflin, and Justin B. Dimick, "Trends in the Adoption of Robotic Surgery for Common Surgical Procedures," *JAMA Network Open* 3, No. 1 (2020): 1-9.

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 150 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [260] Tewari, Krishnansu S., "Minimally Invasive Surgery for Early-Stage Cervical Carcinoma: Interpreting the Laparoscopic Approach to Cervical Cancer Trial Results," *Journal of Clinical Oncology* 37, No. 33 (2019): 3075-3080.
- [261] Tirole, Jean, "The Analysis of Tying Cases: A Primer," *Competition Policy International* 1, No. 1 (2005): 1-25.
- [262] Werden, Gregory, "The History of Antitrust Market Delineation," *Marquette Law Review* 76, No. 1 (1992): 123-215.
- [263] White, Lawrence, "Market Power and Market Definition in Monopolization Cases: A Paradigm is Missing," Wayne D. Collines, ed., *Issues in Competition Law and Policy*, American Bar Association (2008).

Public Sources

- [264] "Board Book," Mississippi Board of Trustees of State Institutions of Higher Learning, January 17, 2019, accessed January 7, 2023, http://www.ihl.state.ms.us/board/downloads/boardbooks/1901
- [265] "Da Vinci X/Xi Instrument & Accessory Catalog," October 2021, Intuitive Surgical, Inc., accessed January 6 2023, https://www.intuitive.com/en-us/-/media/ISI/Intuitive/Pdf/xi-x-ina-catalog-no-pricing-us-1052082.pdf
- [266] "Clinical Evidence," Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/about-us/company/clinical-evidence
- [267] "Company Fact Sheet," Asensus Surgical, accessed January 5, 2023, https://asensus.com/sites/default/files/media-kit/Asensus%20Fact%20Sheet%20-%202021
- [268] "Da Vinci Surgical System 2022 U.S. Coding and Reimbursement Guide," Intuitive Surgical, Inc., accessed January 16, 2023, https://www.intuitive.com/en-us/-/media/Project/Intuitive-surgical/files/pdf/intuitive-da-vinci-reimbursement-and-coding-guide-1086609?la=en&hash=8165652F394F52049A8C6B333AFACDA8
- [269] "Da Vinci Xi Single-Site Technology: Solutions for Single-Incision Surgery," Intuitive Surgical, Inc., accessed January 11, 2023, https://www.intuitive.com/en-us/-/media/Project/Intuitive-surgical/files/pdf/1025290ra-isi-brochure-single-site-digital-low-res-394110?la=en&hash=F24EC0B5DB9C62BDD688F77409A3CA50
- [270] "Horizontal Merger Guidelines," August 19, 2010, U.S. Department of Justice, accessed January 4, 2023, https://www.justice.gov/atr/horizontal-merger-guidelines-08192010
- [271] "Robotic-Assisted Surgery (RAS) Analyst Update," Medtronic, September 24, 2019, accessed January 12, 2023, https://investorrelations.medtronic.com/download/MDT+RAS+Investor+Update+09242019
- [272] "Sustainability Report 2020," Intuitive Surgical, Inc., accessed January 16, 2023, https://isrg.gcs-web.com/static-files/15edd98b-4896-4bd7-a3b4-e2f095a61a61

Websites

- [273] "About the da Vinci Surgical System," UC Health, accessed January 6, 2023, https://www.uchealth.com/services/robotic-surgery/patient-information/davinci-surgical-system/
- [274] "About Us," IQVIA, accessed January 16, 2023, https://www.iqvia.com/about-us
- [275] "About Us," Surgical Instrument Service Company, accessed January 3, 2023, https://sis-usa.com/about/.
- [276] "About Us," Trinity Health, accessed January 5, 2023, https://www.trinity-health.org/about-us/
- [277] "Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication," U.S. Food & Drug Administration, February 28, 2019, accessed January 6, 2023, https://www.fda.gov/medical-devices/safety-communications/update-caution-robotically-assisted-surgical-devices-mastectomy-fda-safety-communication
- [278] "Certified Surgical Instrument Repair Services," Benjamin Biomedical, accessed January 5, 2023, https://benjaminbiomedical.com/
- [279] "Computer-Assisted Surgical Systems," U.S. Food and Drug Administration, accessed January 16, 2023, https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems
- [280] "Contact," Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/about-us/contact.
- [281] "Da Vinci Instruments Trusted dexterity," Intuitive Surgical, Inc., accessed January 6, 2023, https://www.intuitive.com/en-us/products-and-services/da-vinci/instruments.

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 151 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

- [282] "Exploring Surgery Options: Open vs. Minimally Invasive," Beaumont, accessed January 16, 2023, https://www.beaumont.org/health-wellness/blogs/exploring-surgery-options-open-vs-minimally-invasive.
- [283] "Flexible 'open architecture' instrumentation," Medrobotics, accessed January 6, 2023, https://www.easmed.com/surgical-robot-flex-system/
- [284] "Gynecologic Surgery," Valley Medical Center, accessed January 11, 2023, https://www.valleymed.org/services/all-specialties/obgyn-services/gynecologic-surgery
- [285] "How do hospitals make Purchasing Decisions?" Cleve Holden, accessed January 11, 2023, https://www.linkedin.com/pulse/how-do-hospitals-make-purchasing-decisions-cleve-holden
- [286] "How many years of postgraduate training do surgical residents undergo?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/training.
- [287] "Ion by Intuitive," Intuitive Surgical, Inc., accessed January 12, 2023, https://www.intuitive.com/en-us/products-and-services/ion.
- [288] "Jean Tirole Facts," The Nobel Prize, accessed January 6, 2023, https://www.nobelprize.org/prizes/economic-sciences/2014/tirole/facts/
- [289] "MAUDE Manufacturer and User Facility Device Experience," U.S. Food and Drug Administration, accessed January 6, 2023, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
- [290] "Methods of Surgery," Johns Hopkins Medicine, accessed January 5, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/methods-of-surgery ("Johns Hopkins Medicine").
- [291] "Professional versus facility billing: What hospitalists must know," Larry Beresford, June 15, 2021, accessed January 16, 2023, https://www.the-hospitalist.org/hospitalist/article/241539/mixed-topics/professional-versus-facility-billing-what-hospitalists-must.
- [292] "Real World Data Sets," IQVIA, accessed January 6, 2023, https://www.iqvia.com/solutions/real-world-evidence/real-world-data-and-insights.
- [293] "Reimbursement Resources," Intuitive Surgical, Inc., accessed January 5, 2023, https://www.intuitive.com/en-us/about-us/company/reimbursement
- [294] "Robotic Surgery," Mayo Clinic, accessed January 12, 2023, https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974
- [295] "Robotic-Assisted Surgery with da Vinci Systems," Intuitive Surgical, Inc., accessed January 16, 2023, https://www.intuitive.com/en-us/patients/da-vinci-robotic-surgery
- [296] "Services," Surgical Instrument Service Company, accessed January 3, 2023, https://sis-usa.com/services/.
- [297] "Side Effects of Surgery," Cancer.Net, accessed January 5, 2023, https://www.cancer.net/navigating-cancer-care/how-cancer-treated/surgery/side-effects-surgery; Anna Pinto et al., "Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis," BMJ Open (2016): 1-23.
- [298] "Statement on Credentialing and Privileging and Volume Performance Issues," American College of Surgeons, April 1, 2018, accessed January 5, 2023, https://www.facs.org/about-acs/statements/111-credentialing
- [299] "Statements on Principles," American College of Surgeons, accessed January 16, 2023, https://www.facs.org/about-acs/statements/stonprin
- [300] "The Senhance Surgical System is the first and only digital laparoscopic platform," Senhance, accessed January 6, 2023, https://www.senhance.com/us/digital-laparoscopy
- [301] "TransEnterix Announces Name Change to Asensus Surgical and Introduces a New Category of Surgery, Performance-Guided Surgery," Business Wire, February 23, 2021, accessed January 6, 2023, https://www.businesswire.com/news/home/20210223005444/en/TransEnterix-Announces-Name-Change-to-Asensus-Surgical-and-Introduces-a-New-Category-of-Surgery-Performance-Guided-Surgery
- [302] "Understanding your Hospital Bill," MedlinePlus, accessed January 16, 2023, https://medlineplus.gov/ency/patientinstructions/000881.htm
- [303] "What are the surgical specialties?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/specialties.

Case 3:21-cv-03496-AMO Document 230-8 Filed 05/17/24 Page 152 of 152 HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

[304] "What is the job description for surgeons?" American College of Surgeons, accessed January 16, 2023, https://www.facs.org/education/resources/medical-students/faq/job-description.